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Claigan PFAS Submission #5

PFAS Derogations and Justifications

Derogations needed for PFAS applications necessary for society without effective substitutes

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Table of Contents

1. Summary

This report is submission #5 of 5 by Claigan Environmental Inc. (Claigan) on behalf of the EU PFAS Restriction Submission Project ("PFAS Submission Project"). The PFAS submission project is made up of dozens of companies from a wide range of industries (consumer, professional, industrial, medical, oil and gas, laboratory equipment, textiles, electronic components, and retail sales.)

The PFAS Submission Project is focused primarily on the needs of complex products (articles.) Claigan is both a restricted materials consultancy and a high-volume restricted materials testing laboratory. Each of the PFAS Submission Project submissions is based on contributions from all major sectors of industry and 2023 PFAS testing data from complex products.

This report (#5) is a detailed itemization and justification of each derogation of PFAS uses that are necessary for the functioning of society and do not have adequate replacements. These derogations are application-based, as opposed to industry-based. The reason for the use of a PFAS material is normally performance related and not necessarily related to any one industry segment. Many different industries have common critical performance characteristics.

The derogations below are based on

- Feedback from a wide range of industries
- A review of substitutes (see Claigan EU PFAS Submission Project Report #4) and the availability of adequate substitutes
- Detailed testing data of the polymers themselves and PFAS additives / degradation products commonly found in those materials (Claigan EU PFAS Submission Project Reports #1 and #2)
- Risk of harm to the environment (Claigan EU PFAS Submission Project Report #3)
- Socio-economic impact

Important note - due to the short timeline of the EU PFAS Restriction Consultation, each justification is only in brief. Each justification can be further elaborated upon, if needed.

Important comment - Fluoropolymers and fluoroelastomers in industrial and medical applications should NOT be restricted in haste. In many cases, 13.5 years were requested in the derogations below based on the recommendation for materials currently without suitable replacements. However, unlimited-duration derogations for fluoropolymers in any industrial and medical applications is recommended until viable and proven alternatives are developed. The risk to humans and the environment due to material substitution is significant in these applications.

In a number of industrial or scientific cases, such as piezo/ferroelectric PVDF, identification of a suitable replacement material would require a scientific breakthrough of Nobel prize significance.

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2. Summary of Derogations Requested

Note - some derogations have been removed (example - c1) as it was either a duplicate of a more specific derogation, or it did not meet the justification requirements.

Derogation	Timeline Requested	Derogation	Tonnage per Year	Text for Derogations
c2	13.5 Years	PFAS Polymers	100-1,000 tons	Fluoropolymer and perfluoropolyether (PFPE) release agents used in manufacturing processes of plastic and rubber parts including foam.
c3a	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE used as an additive drip agent in plastics to meet flammability safety requirements
c3b	13.5 Years	PFAS Polymers	10-100 tons	PFBS (and its salts) for the purposes of plastic clarity in flame retarded polymers under 1,000 ppm of the plastic
c4a	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE, ETFE, FEP, and PFA used for electrical insulation purposes except wiring.
c4b	13.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	Fluorosilicone, amorphous fluoro resins, and fluoroelastomers (including perfluoroelastomers) for electrical insulation purposes except wiring.
c5a	13.5 Years	PFAS Polymers and Non-Polymers	100-1,000 tons	Fluoropolymers in invasive, implantable, fluid, and gas contacting applications in medical devices.
c5b	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Maximum of 2ppm C4-C14 perfluoroalkyl carboxylates in fluoropolymers in invasive, implantable, fluid, and gas contacting applications in medical devices.

c6a	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE as an additive up to 25% in plastics for the purposes reduced friction and wear
c6b	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE, ETFE, and PCTFE for professional, industrial, or high temperature applications (>150C) requiring reduced friction, or chemical inertness.
c7	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE, ETFE, PFA, PVDF, and FEP as a wire insulator.
c8a	13.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	Fluoroacrylic coatings necessary for chemical safety for fabrics. Maximum of 5ppm sum of C4-C18 perfluoroalkyl carboxylates.
c8a	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Fluoroacrylic coatings on fabrics necessary for the protection or storage of portable medical devices or laboratory equipment. Maximum of 5ppm sum of C4-C18 perfluoroalkyl carboxylates.
c9	13.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	PTFE and PVDF filter membranes for gas and aqueous filtration. Maximum of 20ppm of C4-C14 perfluoroalkyl carboxylates
c10	13.5 Years	PFAS Polymers	10-100 tons	PTFE as a lubricant additive under 30% concentration not in contact with drinking water.
c11a	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE as a fused coating on cookware
c11b	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE as a coating for chemical containers
c12a	13.5 Years	PFAS Polymers and Non-Polymers	100-1,000 tons	Fluoroelastomers (including perfluoroelastomers), fluorosilicone, and amorphous fluoro resins as a sealing material in situations requiring chemical resistance, oil resistance, oxidation resistance, decompression resistance, high temperature (over 150C), or low temperature (<-20C).

c12b	13.5 Years	PFAS Polymers and Non-Polymers	10 to 100 tons	Fluoroelastomers (including perfluoroelastomers), fluorosilicone, and amorphous fluoro resins as a sealing material for drinking water or food contact if compliant with EU drinking water directives and regulations.
c13a	13.5 Years	PFAS Polymers and Non-Polymers	100-1,000 tons	PTFE tape for moisture insulation, or joining of fluid or gas components. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates for 6.5 years
c13b	13.5 Years	PFAS Polymers and Non-Polymers	100-1,000 tons	PTFE tape for reduction of friction. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates for 6.5 years
c14	6.5 Years	PFAS Polymers	0-10 tons	Fluorosilcone release paper and residual fluorosilicone on adhesive products.
c16	13.5 Years	PFAS Polymers	10-100 tons	Fluorocoating of rubber, metal, and plastic seals in professional or industrial applications where chemical resistance is required
c17	13.5 Years	PFAS Polymers	10-100 tons	PTFE and PFA coating of metal for environmental or temperature resistance not in contact with food or drinking water
c18	13.5 Years	PFAS Polymers	10-100 tons	PTFE, FEP, and PFA coating of metal for low friction and wear resistance in machinery or tools
c19	13.5 Years	PFAS Polymers	10-100 tons	PTFE, PFA, FEP, and TFE copolymers in hoses in chemical, pump, or valve applications.
c20	6.5 Years	PFAS Polymers	0-10 tons	Fluorocoatings on labels on products (excluding textiles) necessary for environmental resistance
c21	13.5 Years	PFAS Polymers and Non-Polymers	100-1,000 tons	PTFE, PFA, FEP, PVDF, ETFE, and fluoroelastomer (including perfluoroelastomer) tubing not in contact with drinking water. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates
c22	13.5 Years	PFAS Non-Polymers	10-100 tons	Heat transfer fluids for industrial applications

c23a	13.5 Years	PFAS Polymers	1,000-10,000 tons	PVDF and PTFE as the cathode binder in lithium batteries
c23b	13.5 Years	PFAS Polymers	10-100 tons	PVDF, PTFE, TFE, and sulfonated PTFE as a binder or spacer in capacitors
c24	6.5 Years	PFAS Polymers	10-100 tons	PTFE and fluorosilicone lubricants for internal wires
c25	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Surfactants in emulsion based bio-assays and dry-chemistry assays
c26	13.5 Years	PFAS Polymers	0-10 tons	PTFE foil coating of rubber for biotechnology or chromatography purposes
c27	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Products used for education or training purposes may use derogations applicable to products they are simulating.
c28	13.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	Fluorinated polyethylene for chemical storage and handling. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates
c29	13.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	ePTFE as a gasket / seal material in professional applications. Maximum of 5ppm of C4-C14 perfluoroalkyl carboxylates
c31a	6.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	Fluoro acrylics for antismudge and antireflective coatings for plastics. Maximum of 1ppm of C4-C6 perfluoroalkyl carboxylates. Maximum of 1ppm of C7-C14 perfluoroalkyl carboxylates.
c31b	13.5 Years	PFAS Polymers	10-100 tons	Fluorosilicone and nano-fluorocoatings for antismudge and antireflective coatings for plastics and glass.
c32a	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE, PCTFE, PVDF, FEP, and TFE (including copolymers) as a sealing or spacer material.
c32b	13.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	PFA as a sealing or spacer material in professional applications.

c33	13.5 Years	PFAS Polymers	10-100 tons	PVDF and ETFE as a component in fluid or gas systems
c34	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	PTFE in coatings of labels for security or tamper evidence. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates.
c35	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Fluoroacrylic and PFA coatings (and solvents) for encapsulation of capacitors or semiconductor components. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates and 10ppm residual fluoroethers
c36	13.5 Years	PFAS Polymers	100-1,000 tons	PTFE and fluorosilicone sprays for maintaining lubrication in industrial equipment.
c37	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Ionic fluoro fluids as electrolytes in capacitors or batteries
c38	13.5 Years	PFAS Polymers	10-100 tons	Perfluorinated polyether (PFPE) as a lubricant for harsh environments
c40	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Maximum of 5ppm of C4-C14 perfluoroalkyl carboxylates in derogated applications of PFA
c41	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Maximum of 10 ppm 6:2 FTS, 5ppm C4-C6 perfluoroalkyl carboxylates, and 10 ppm bisphenol AF in derogated applications of fluoroelastomers and perfluoroelastomers
c43	13.5 Years	PFAS Polymers	0-10 tons	PVDF polymers and PVDF terpolymers for ferroelectric films.
c44	6.5 Years	PFAS Polymers and Non-Polymers	10-100 tons	Fluoroethers for degreasing applications
c45	13.5 Years	PFAS Polymers	10-100 tons	Residual hydrofluoroolefins used as blowing agents for insulating foam internal to products

c46	13.5 Years	PFAS Polymers	0-10 tons	PTFE as a manufacturing aid or tool for high temperature (> 150C) applications
c48	13.5 Years	PFAS Polymers and Non-Polymers	0-10 tons	Fluorocoatings on laser fibers, laser fiber components, and fibers for optical purposes including light guidance.
c51	13.5 Years	PFAS Polymers	0-10 tons	F2 gas fluorinated plastics in capacitors and microchips
c52	13.5 Years	PFAS Polymers	0-10 tons	PTFE filled die attach material for semiconductor devices

3. Related documents

3.1. Claigan PFAS Submission #1 - PFAS in Articles

3.1.1. Comprehensive 2023 testing data regarding locations and uses of PFAS in articles.

3.2. Claigan PFAS Submission #2 - PFOA in Articles

3.2.1. 2022 and 2023 test data regarding PFOA (and other perfluorocarboxylates and perfluorosulfonates in articles)

3.3. Claigan PFAS Submission #3 - PFAS in Drinking Water

3.3.1. Evaluation of recent news articles and related science papers on PFAS in drinking water and in human blood.

3.4. Claigan PFAS Submission #4 - PFAS Substitutes and Alternatives

3.4.1. A review of the pros and cons of fluoropolymers and their potential substitutes.

4. Definitions

4.1. Text for derogation

4.1.1. The simple text to include in the derogation of REACH restriction for PFAS

4.2. Alternative text

4.2.1. Alternative text (if applicable) for the derogation.

4.3. Uses and Functionality

4.3.1. A longer explanation of the use and details of the requested derogation.

4.4. Substitutes / Alternatives

4.4.1. An evaluation of availability of effective, validated, and available substitutes

4.4.2. Due to the short timeline for submission to the consultation, the explanation of alternatives for each requested derogation is brief. Further details can be provided in each situation.

4.4.3. In most applications, once the material properties are reviewed, the justification of the use is fairly obvious due to temperature, safety, or environmental conditions.

4.4.4. See Claigan EU PFAS Submission Report #4 - Comparison of Substitutes for further details.

4.5. Forever Chemicals

4.5.1. Risk of perfluorocarboxylates (PFOA family) and perfluorosulfonates (PFOS family) in the use.

4.5.1.1. Plus explanation, if relevant, for fluorinated salts that are not classified vPvB or PBT substances.

4.5.2. A detailed explanation for each material is in Claigan EU PFAS Submission #2 - PFOA in Products and Claigan EU PFAS Submission #4 - Comparison of Alternatives.

4.6. Number of companies affected

4.6.1. Estimate of the number of companies affected.

4.6.1.1. Note - number of companies is a misleading statistic as companies are of different order of magnitude of sizes and a straight count can be misleading.

4.7. Annual Tonnage

4.7.1. Expected annual tonnage of the PFAS substance imported into or manufactured for use in the EU each year.

4.8. Timeline Requested

4.8.1. 6.5 years - Substitutes available but replacement and re-qualification of the related products will take time

4.8.2. 13.5 years - Substitutes are not currently available and are not expected to be available in the near future.

5. C2 - Fluoropolymer and Perfluoropolyether Release Agents

5.1. Text for derogation

5.1.1. Fluoropolymer and Perfluoropolyether (PFPE) release agents used in manufacturing processes of plastic and rubber parts including foam.

5.2. Alternative text

5.2.1. n/a

5.3. Use and Functionality

5.3.1. Fluoropolymer and PFOE release agents are commonly used in the molds for rubber, plastic, and foams materials. The most common applications of mold release agents are in the manufacturing of o-rings, gaskets, and foam. Roughly 25% of o-rings / gaskets in physical products have residual release agents on the surface above 100 ppm fluorine.

5.3.2. Without effective release agents, the rubber, plastic, or foam part would adhere partially to the mold and suffer defects.

5.4. Substitutes / Alternatives

5.4.1. Silicone mold release agents would be a suitable replacement for PFAS release agents in most applications, however the use of PFAS release agents are so prevalent in manufacturing that the conversion and re-qualification process will take years.

5.5. Forever Chemicals

5.5.1. None expected.

5.5.1.1. Due to the low concentration of fluorocoating, no measurable PFAS forever chemicals over 25 ppb is expected.

5.6. Number of companies affected

5.6.1. 10,000+

5.7. Annual Tonnage

5.7.1. 100-1,000 tons per annum.

5.8. Timeline Requested

5.8.1. 13.5 years - Substitutes available but replacement and re-qualification of the related products will take significant time. 6.5 years would not be sufficient time as it would take years to find all the occurrences even in an individual product let alone a product family.

5.8.2. Roughly ¼ of all gaskets and seals use fluoro release agents in their manufacturing process and there is currently no universal effective and accepted test method for its detection.

5.8.3. Unlike the removal of Pb during RoHS, the test standards for low concentration of this material are still not widely adopted or even have basic consensus. Combustion Ion Chromatography (CIC) was heralded as a measured tool for fluorine concentration but is unable to detect mold release agents on the surface of plastics and rubbers. Until widespread adoption of WDXRF (years away), the simple matter of detecting this substance in products is not easily possible.

5.8.4. Supported by document [Draft] PFOA in articles 2023 (#2) section 5 and document [Draft] PFAS alternative and substitutes (#4) section 4

6. C3a - PTFE Anti-Drip Additive

6.1. Text for derogation

6.1.1. PTFE used as an additive drip agent in plastics to meet flammability safety requirements

6.2. Alternative text

6.2.1. n/a

6.3. Use and Functionality

6.3.1. To meet UL94 and similar EU flame retardancy standards, a plastic cannot 'drip' molten plastic when exposed to flame. Many plastics, such as ABS or PC, drip molten plastic when exposed to flame creating both a safety hazard to the user and potentially causing the fire to spread.

6.3.2. PTFE, when added to plastic, creates a 'webbing' during burning - trapping the plastic and preventing dripping of the plastic.

6.3.3. The use of PTFE anti-drip agents is very common in products requiring high flame retardancy, in particular electronics. Plastic parts that normally contain anti-drip agents are plastic housing of electronic products.

6.4. Substitutes / Alternatives

6.4.1. There are currently no effective replacements for PTFE as an anti-drip additive. Virtually all electronics use PTFE anti-drip agents in one or more parts. Restriction of PTFE anti-drip agents would create a significant safety risk for electronics and require the redesign and re-qualification of safety of virtually every electronic product on the EU market.

6.5. Forever Chemicals

6.5.1. None expected.

6.5.1.1. Pure unirradiated PTFE powder used as an anti-drip additive does not contain forever chemicals and has no expectation of degrading into forever chemicals.

6.5.1.1.1. Even in the rare case of an uncontrolled burn, the degradation products are not forever chemicals (no perfluorocarboxylates or perfluorosulfonates). See https://www.fluoridealert.org/wp-content/pesticides/teflon.decomposition.prod.htm.

6.6. Number of companies affected

6.6.1. 10,000+

6.7. Annual Tonnage

6.7.1. 100-1,000 tons per annum.

6.8. Timeline Requested

6.8.1. 13.5 years - Wide spread use, no suitable replacement, no forever chemicals, and substitution creates a significant safety risk.

7. C3b - PFBS as a Clarity Additive

7.1. Text for derogation

7.1.1. PFBS (and its salts) for the purposes of plastic clarity in flame retarded polymers under 1,000 ppm of the plastic.

7.2. Alternative text

7.2.1. n/a

7.3. Use and Functionality

7.3.1. Flame retardant additives to transparent polycarbonate (and similar materials) tends to create a hazy or opaqueness

7.3.2. The addition of trace levels of PFBS (or its salts) maintains the transparency of the plastic.

7.3.3. Transparency and flame retardancy are critical criteria for a number of applications including electronic displays or construction materials.

7.4. Substitutes / Alternatives

7.4.1. There are currently no effective replacements for PFBS as a clarifying additive for flame retardant transparent plastics.

7.5. Forever Chemicals

7.5.1. None expected.

7.5.1.1. Note - PFBS would be present in the product <1,000 ppm. However PFBS is not currently classified as a vPvB or PBT chemical in the EU.

7.6. Number of companies affected

7.6.1. 100 - 1,000

7.7. Annual Tonnage

7.7.1. 10 - 100 tons per annum.

7.8. Timeline Requested

7.8.1. 13.5 years - Wide spread use, low concentration use, and no suitable replacement.

8. C4a - PTFE and ETFE for electrical insulation

8.1. Text for derogation

8.1.1. PTFE, ETFE, FEP, and PFA used for electrical insulation purposes except wiring.

8.2. Alternative text

8.2.1. n/a

8.3. Use and Functionality

8.3.1. PTFE, ETFE, and similar fluoropolymers have very low dielectric constants which makes both materials excellent electrical insulators.

8.3.2. These materials are primarily used in connectors and electronic components for electrical insulation. The most visually obvious uses are the white 'ring' inside a coaxial connector or the white centre core of a wireless router antenna.

8.3.3. PTFE and ETFE spacers include any application that requires electrical insulation including spacers / separators in batteries or capacitors.

8.3.4. Due to the volume of use and different critical properties, PTFE and ETFE wire insulation is covered in a different derogation request.

8.4. Substitutes / Alternatives

8.4.1. No other material has equivalent dielectric constant / electrical insulation capability.

8.4.2. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of performance and biocompatibility of alternatives.

8.5. Forever Chemicals

8.5.1. None expected in initial material nor is material expected to degrade into forever chemicals.

8.5.1.1. The exception is PFA which can have a small amount of perfluorocarboxlates from degradation of its C-O-C side chain bond. PFA can be made without perfluorocarboxylate degradation, but it will take time to replace. There is a separate derogation request for phase out of perfluorocarboxylates in PFA.

8.5.1.2. PFA represents <1% of fluoropolymers in dielectrics / insulators.

8.6. Number of companies affected

8.6.1. 10,000+ companies

8.7. Annual Tonnage

8.7.1. 100 - 1,000 tons per annum.

8.8. Timeline Requested

8.8.1. 13.5 years - Wide spread use, no forever chemicals, and no suitable replacement.

9. C4b - Fluoroelastomers for electrical insulation

9.1. Text for derogation

9.1.1. Fluorosilicone, amorphous fluoro resins, and fluoroelastomers (including perfluoroelastomers) for electrical insulation purposes except wiring.

9.2. Alternative text

9.2.1. n/a

9.3. Use and Functionality

9.3.1. Fluoroelastomers (and similar materials) have low dielectric constants which makes both materials good electrical insulators.

9.3.2. PTFE and ETFE have limited flexibility and fluoroelastomers are required to meet both the electrical insulation and flexibility requirements.

9.3.3. Common products using fluoroelastomers for electrical insulation would be electronic products such as hard drives. The use in hard drives (among very many other electronics applications) affects a large number of companies.

9.3.4. Fluorosilicone, amorphous fluoro resins, fluoroelastomers (FKM), and perfluoroelastomers (FFKM) have very similar performance and materials characteristics and are recommended to be covered under the same derogation.

9.4. Substitutes / Alternatives

9.4.1. No other material has equivalent dielectric constant / electrical insulation capability with flexibility

9.4.2. Fluoroelastomer use is more specialized and lower volume than PTFE and ETFE for the same purpose.

9.5. Forever Chemicals

9.5.1. Fluoroelastomers and perfluoroelastomers require a sulfonated fluorotelomer surfactant as part of their emulsion polymerization manufacturing process. The resulting 6:2 FTS, and short chain perfluorocarboxylates are covered in derogation request c41a.

9.5.2. All of the fluorosulfonates or fluorocarboxyles present are short chain chemicals and none are classified vPvB or PBT substances.

9.6. Number of companies affected

9.6.1. 10,000+ companies

9.7. Annual Tonnage

9.7.1. 10 - 100 tons per annum.

9.8. Timeline Requested

9.8.1. 13.5 years - Wide spread use, no forever chemicals, and no suitable replacement.

10. C5a - Fluoropolymers in invasive / implantable devices

10.1. Text for derogation

10.1.1. Fluoropolymers in invasive, implantable, fluid, and gas contacting applications in medical devices.

10.2. Alternative text

10.2.1. n/a

10.3. Use and Functionality

10.3.1. Fluoropolymers are very low friction, hydrophobic, oleophobic (oil resistance) and very biocompatible making them ideal for medical devices.

10.3.2. Uses include an almost infinite number of implantable or invasive applications such as tubing, wiring, protective coatings, bearings, and a wide assortment of fluid and gas components.

10.3.3. Unlike other products, implantable and invasive medical devices undergo rigorous chemical safety testing which include PFOA and similar chemicals. Each implantable or invasive device is tested for PFOA (and similar) extractables and reviewed for toxicology.

10.3.3.1. Note - the testing described above only applies to invasive or implantable medical devices. Medical devices that are not implantable or invasive do not undergo the same testing (neither does IVD medical devices). These devices would have requirements for PFAS materials for their continued function, but the applications would overlap with other applications for other industries.

10.4. Substitutes / Alternatives

10.4.1. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of performance and biocompatibility of alternatives.

10.4.2. No other material has the same performance requirements (low friction, high biocompatibility) as fluoropolymer materials. In the cases where forever chemicals are present in fluoropolymers in medical devices, the

material was chosen for very specific performance criteria (such as flexibility) not available with standard PTFE.

10.5. Forever Chemicals

10.5.1. Due to the use of irradiated PTFE, expanded PTFE (ePTFE), and PFA in medical devices - the full range of perfluorocarboxylates (PFOA family) are present at >100 ppb per chemical in ~25% of PFAS uses in medical devices.

10.5.2. Any approval of fluoropolymers for implantable / invasive applications will need approval for perfluorocarboxylates (PFOA family). Due to material performance requirements, perfluorocarboxylates are currently unavoidable in implantable and invasive devices.

10.6. Number of companies affected

10.6.1. 1,000+ companies

10.7. Annual Tonnage

10.7.1. 100 - 1,000 tons per annum.

10.8. Timeline Requested

10.8.1. 13.5 years - No suitable replacements, high human safety risk, and length re-qualification required

11. C5b - Fluoroelastomers in invasive / implantable devices

11.1. Text for derogation

11.1.1. Fluorosilicone, amorphous fluoro resins, and fluoroelastomers (including perfluoroelastomers) for electrical insulation purposes except wiring.

11.2. Alternative text

11.2.1. n/a

11.3. Use and Functionality

11.3.1. Fluoroelastomers (FKM) and perfluoroelastomers (FFKM) are low friction, hydrophobic, oleophobic (oil resistance) and very biocompatible making

them ideal for medical devices. Fluoroelastomers have more rubber characteristics than fluoropolymers such as PTFE, and are needed for medical applications requiring a rubber over a plastic.

11.3.2. Uses include a large range of biocompatible rubber applications in medical devices including seals, strain relief, and other applications requiring a biocompatible rubber over a plastic.

11.3.3. Unlike other products, implantable and invasive medical devices undergo rigorous chemical safety testing which includes PFOA and similar chemicals. Each implantable or invasive device is tested for PFOA (and similar) extractables and reviewed for toxicology.

11.3.3.1. Note - this testing only applies to invasive or implantable medical devices. Medical devices, not implantable or invasive, do not undergo the same testing (neither does IVD medical devices). These devices would have requirements for PFAS materials for their continued function, but the applications would overlap with other applications for other industries.

11.3.4. This derogation includes four (4) different similar fluororubbers (fluorosilicone, amorphous fluoro resin, fluoroelastomer (FKM), and perfluoroelastomer (FFKM).

11.4. Substitutes / Alternatives

11.4.1. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of performance and biocompatibility of alternatives.

11.4.2. No other rubber material has the same performance requirements (low friction, high biocompatiblity) as fluoropolymer materials.

11.4.3. For example - Silicone rubber averages 100x higher concentrations of forever chemicals (D4, D5, and D6 - which are EU classified PBTs) than fluoroelastomers, is likely subject to REACH restriction in the near future in the EU (due to D4, D5, and D6 monomers restriction proposed under POP), has much higher friction, and has poor resistance to oils.

11.5. Forever Chemicals

11.5.1. Fluoroelastomers and perfluoroelastomers require a fluorinated surfactant for emulsion polymerization and bisphenol AF for crosslinking. These materials cannot currently be made reliably without these manufacturing aids.

11.5.2. Any approval of fluoroelastomers for implantable / invasive applications will need approval of 6:2 FTS fluorotelomer sulfonates (and substances that degrade into 6:2 FTS), and approval for a low concentration of short chain perfluorocarboxylates that degrade from 6:2 FTS (C4 to C7 perfluorocarboxylates). Approval will also be required for low concentrations of residual bisphenol AF crosslinking additives.

11.6. Number of companies affected

11.6.1. 100-1,000 companies

11.7. Annual Tonnage

11.7.1. 10 - 100 tons per annum.

11.8. Timeline Requested

11.8.1. 13.5 years - No suitable replacements, high human safety risk, and length re-qualification required.

12. C6a - PTFE additive to plastics for wear reduction

12.1. Text for derogation

12.1.1. PTFE as an additive up to 25% in plastics for the purpose to reduce friction and wear

12.2. Alternative text

12.2.1. PTFE as an additive in plastics for the purpose to reduce friction and wear

12.3. Use and Functionality

12.3.1. The addition of PTFE powder to standard plastics such as nylon reduces the coefficient of friction of the plastic by up to 60%.

12.3.2. Used in a wide range of plastic components that turn against the surface of another plastic or metal. PTFE added plastics are commonly used in

fluid, gas, machinery, and electronics applications. Fluid and gas uses are generally (but not exclusively) valves and similar components with potential for wear, plastic gears in machinery (including consumer products), and connectors (with a turn lock type function) in electronics.

12.4. Substitutes / Alternatives

12.4.1. No other additives are as effective to safely reduce the coefficient of friction of plastics. Restriction of PTFE additives in plastics for friction reduction would reduce the lifetime of many products, resulting in products going to waste or landfall sooner and more often.

12.4.2. In addition, PTFE added plastics extend product life/service intervals thereby reducing potential fluid and gas releases/exposures. They also reduce power consumption compared to non-PTFE added counterparts.

12.5. Forever Chemicals

12.5.1. None expected. Unirradiated PTFE powder has no forever chemicals.

12.5.2. Irradiated PTFE powder is not needed and would be restricted by current PFOA and long chain perfluorocarboxylate restrictions (POP and REACH) in the EU.

12.6. Number of companies affected

12.6.1. 10,000+ companies

12.7. Annual Tonnage

12.7.1. 1000+ tons per annum.

12.8. Timeline Requested

12.8.1. 13.5 years - No suitable replacements and no forever chemicals or risk to drinking water / humans.

13. C6b - PTFE, ETFE, and PCTFE for low friction parts and chemical inertness

13.1. Text for derogation

13.1.1. PTFE, ETFE, and PCTFE for professional, industrial, or high temperature applications (>150C) requiring reduced friction, or chemical inertness.

13.2. Alternative text

13.2.1. PTFE, ETFE, and PCTFE for applications requiring reduced friction or chemical inertness in machinery (including consumer and professional applications).

13.3. Use and Functionality

13.3.1. The use of PTFE, ETFE, and PCTFE as a material for parts requiring low friction or chemical inertness in products.

13.3.2. The uses are parts that require either low friction (such as plastic gears or bearings) or have a role in hostile chemical environments (a bracket in a chemical bath, brushes in a chemical environment, or wafer cassette for semiconductor manufacturing) other than as a seal. PTFE in seals are covered in another derogation request as that application is more specific.

13.3.3. Consumer applications at temperatures exceeding 150C would be included in this derogation. Potentially compromising high temperature safety in a household would not be recommended without significant review and validation.

13.3.4. The text of the derogation here is limited to non-consumer products unless high temperature is required, however due to the low risk of these materials, an alternative text to extend to consumer products under the same conditions is included.

13.4. Substitutes / Alternatives

13.4.1. No other materials have the same low friction and chemical inertness properties as PTFE, ETFE and PCTFE at regular temperatures and at high temperature (150C).

13.4.2. PTFE and PCTFE extend product life/service intervals thereby reducing potential chemical releases/exposures. They also can reduce power consumption compared to non-PTFE/PCTFE counterparts.

13.4.3. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of friction, chemical resistance, and temperature resistance.

13.5. Forever Chemicals

13.5.1. None expected. Unirradiated PTFE powder has no forever chemicals.

13.5.2. Irradiated PTFE powder is not needed for this application and would be restricted by current PFOA and long chain perfluorocarboxylate restrictions (POP and REACH) in the EU.

13.6. Number of companies affected

13.6.1. 1,000-10,000 companies

13.7. Annual Tonnage

13.7.1. 100-1,000 tons per annum.

13.8. Timeline Requested

13.8.1. 13.5 years - No suitable replacements and no forever chemicals or risk to drinking water / humans.

14. C7 - PTFE, ETFE, PFA, PVDF, and FEP as a wire insulator.

14.1. Text for derogation

14.1.1. PTFE, ETFE, PFA, PVDF, and FEP as a wire insulator.

14.2. Alternative text

14.2.1. n/a

14.3. Use and Functionality

14.3.1. Fluoropolymers are commonly used as wire insulation. These materials have excellent electrical insulation and temperature resistance properties.

14.3.2. These materials are very important wire insulators in high density/temperature environments such as complex electronics (examples - laptops, computers, cell phones) or heating products (examples - ovens, furnaces)

14.3.3. With the move to chlorine free wiring, and the reduction of PVC wiring (and associated phthalate risks), PTFE (and other fluoropolymer wiring) has been the common choice.

14.3.4. Most PTFE (and similar) wiring is internal wiring with very limited exposure to humans or drinking water.

14.4. Substitutes / Alternatives

14.4.1. Silicone has similar temperature resistance to PTFE (and similar) wire insulators, but

14.4.1.1. Requires greater thickness, and is not suitable for dense applications,

14.4.1.2. Contains, on average, more than 100X more forever chemicals than even PFA wire insulation,

14.4.1.3. Is likely to be subject to REACH Restriction due to its constituent monomers (D4, D5, and D6), and

14.4.1.4. Does not hold its shape to the same manner as PTFE (and similar) insulation.

14.4.2. PVC is commonly used in wire applications, however it is not suitable in applications requiring high temperature, reduced friction, or outgassing of substances. PVC is known for outgassing or leaking of hazardous chemicals, and is not suitable for many high performance environments.

14.4.3. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of forever chemicals and temperature resistance.

14.5. Forever Chemicals

14.5.1. None expected for PTFE, FEP, PVDF, and ETFE wire insulation.

14.5.2. PFA wire insulation will commonly contain ~100 ppb for each perfluorocarboxylate (PFOA family) due to degradation of the C-O-C bond in the fluoro side chain. A specific PFA perfluorocarboxylate related derogation is included later in this report.

14.6. Number of companies affected

14.6.1. 10,000+ companies

14.7. Annual Tonnage

14.7.1. 1,000+ tons per annum.

14.8. Timeline Requested

14.8.1. 13.5 years - No suitable replacements, very limited human exposure, and wide usage.

15. C8a - Fluoroacrylic coatings for fabrics for safety reasons

15.1. Text for derogation

15.1.1. Fluoroacrylic coatings necessary for chemical safety for fabrics. Maximum of 5ppm sum of C4-C18 perfluoroalkyl carboxylates.

15.2. Alternative text

15.2.1. n/a

15.3. Use and Functionality

15.3.1. Fluoroacrylates are acrylic polymers with side chain fluorocarbons attached by an ester bond (which includes the weak C-O-C bond subject to degradation with time).

15.3.2. Fluoroacrylate coatings are common for the chemical resistance of fabrics. No other air permeable coatings have the same resistance to water, acids, bases, and oils.

15.3.3. For situations where it is required for the fabric to protect the user from chemicals and air permeability, there are no safe replacements for fluoroacrylate coatings.

15.3.4. The use here is limited to fabrics that provide chemical safety protection to the user and not for general consumer wear.

15.4. Substitutes / Alternatives

15.4.1. No other air permeable coatings have the same resistance to water, acids, bases, and oils.

15.4.2. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of water resistance, oil resistance, and chemical resistance.

15.5. Forever Chemicals

15.5.1. Fluoroacrylates >100 ppb for each perfluorocarboxylate (PFOA family) due to degradation of the C-O-C bond in the fluoro side chain. These chemicals will be present after manufacturing and will continue to accumulate as the weak (low energy of bond dissociation) C-O-C bond of the fluoro side chain fractures producing additional perfluorocarboxylates.

15.5.2. For this usage to continue, fluoroacrylates need to be permitted at least 5 ppm of perfluorocarboxylates.

15.6. Number of companies affected

15.6.1. 100-1,000 companies

15.7. Annual Tonnage

15.7.1. 10 - 100 tons per annum.

15.8. Timeline Requested

15.8.1. 13.5 years - No suitable replacements and significant safety risks if use is restricted.

16. C8b - Fluoroacrylic coatings for fabrics for protection of medical devices

16.1. Text for derogation

16.1.1. Fluoroacrylic coatings on fabrics necessary for the protection or storage of portable medical devices or laboratory equipment. Maximum of 5ppm sum of C4-C18 perfluoroalkyl carboxylates.

16.2. Alternative text

16.2.1. n/a

16.3. Use and Functionality

16.3.1. Fluoroacrylates are acrylic polymers with side chain fluorocarbons attached by an ester bond (which includes the weak C-O-C bond subject to degradation with time).

16.3.2. Fluoroacrylate coatings are common for the chemical resistance of fabrics. No other air permeable coatings have the same resistance to water, acids, bases, and oils.

16.3.3. Sensitive devices such as medical devices or laboratory equipment, in particular portable versions, require strong environmental protection for rugged conditions. Environmental damage could lead to an error with a medical or measuring device, potentially creating harm.

16.3.4. This derogation request is intended to encompass the medical / laboratory devices plus any accessories or reagents. Environmental damage to either risks human harm.

16.4. Substitutes / Alternatives

16.4.1. No other air permeable coatings have the same resistance to water, acids, bases, and oils.

16.4.2. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of water resistance, oil resistance, and chemical resistance.

16.5. Forever Chemicals

16.5.1. Fluoroacrylates >100 ppb for each perfluorocarboxylate (PFOA family) due to degradation of the C-O-C bond in the fluoro side chain. These chemicals will be present after manufacturing and will continue to accumulate as the weak (low energy of bond dissociation) C-O-C bond of the fluoro side chain fractures producing additional perfluorocarboxylates.

16.5.2. For this usage to continue, fluoroacrylates need to be permitted at least 5 ppm of perfluorocarboxylates.

16.6. Number of companies affected

16.6.1. 10-100 companies

16.7. Annual Tonnage

16.7.1. 0 - 10 tons per annum.

16.8. Timeline Requested

16.8.1. 13.5 years - No suitable replacements, low volume application, and significant safety risks if use is restricted.

17. C9 - PTFE and PVDF filter membranes

17.1. Text for derogation

17.1.1. PTFE and PVDF filter membranes for gas and aqueous filtration. Maximum of 20ppm of C4-C14 perfluoroalkyl carboxylates

17.2. Alternative text

17.2.1. PTFE (including ePTFE) and PVDF filter membranes for gas and aqueous filtration. Maximum of 20ppm of C4-C14 perfluoroalkyl carboxylates

17.3. Use and Functionality

17.3.1. Filter membranes which allow gas permeability, but are filter fluids, are very common in medical, laboratory, and industrial applications (but can also be used in specialized consumer applications which require gas permeability with chemical filtration).

17.3.2. PTFE and PVDF filter membranes are strongly hydrophobic and oleophobic while allowing air to pass through. These membranes are also very acid and alkali resistant, allowing a wide range of specialized applications.

17.3.3. PTFE and PVDF filter membranes are normally expanded materials with a fabric-like structure. This derogation request is designed to include PVDF, PTFE, and the expanded form of ePTFE. ePTFE share the same CAS number, but are different materials from a structural and residual chemicals perspective.

17.3.4. In a number of cases, the legislated test method in EU member states requires fluoropolymer permeable membranes.

17.4. Substitutes / Alternatives

17.4.1. No other material has the same gas permeability while being hydrophobic, oleophobic, acid resistance, and alkali resistant. PTFE and PVDF

membranes also have the advantages of maintaining their performance characteristics even at elevated temperatures.

17.4.2. Although it is theoretically possible to develop a porous gas permeable polyethylene frit for some applications, this would be a long project and is risky regarding tightness and reproducibility of the gas transfer.

17.4.3. See Claigan PFAS Submission #4 - comparison of substitutes for a full material by material comparison of forever chemicals and temperature resistance.

17.5. Forever Chemicals

17.5.1. ePTFE normally contains a concentration of ~100 ppb of each of the perfluorocarboxylates (PFOA family). The source of perfluorocarboxylates in ePTFE is not clear, but consistent in ePTFE materials. The likely source is irradiation of the original PTFE powder to 'rubberize' the PTFE to make it more conducive to stretching (expansion) into ePTFE. Irradiation of the initial powder would produce low concentrations of each perfluorocarboxylate chain length as PTFE fragments fractured by radiation from the original long polymer chain will react with oxygen forming perfluorocarboxylates.

17.6. Number of companies affected

17.6.1. 100 - 1,000 companies

17.7. Annual Tonnage

17.7.1. 10 to 100 tons per annum.

17.8. Timeline Requested

17.8.1. 13.5 years - No suitable replacements, very limited human exposure, and very technical application.

18. C10 - PTFE Additive in Grease

18.1. Text for derogation

18.1.1. PTFE as a lubricant additive under 30% concentration not in contact with drinking water.

18.2. Alternative text

18.2.1. PTFE as a lubricant additive for professional applications.

18.3. Use and Functionality

18.3.1. PTFE in mineral oil or silicone oil grease has superior lubrication properties compared to mineral or silicone oil alone.

18.3.2. PTFE added grease is used in a very wide range of applications, primarily for machinery or other moving parts when lubrication for an extended time period is required.

18.3.3. PTFE added grease has both consumer and professional applications.

18.4. Substitutes / Alternatives

18.4.1. No other material has the same impact as a low friction additive to mineral or silicone oil than PTFE.

18.5. Forever Chemicals

18.5.1. None expected

18.5.2. Unirradiated PTFE does not normally contain perfluorocarboxylates and is not expected to degrade into perfluorocarboxlates.

18.5.2.1. Irradiated PTFE would not normally be used as an additive in grease, and would be regulated by current POP and REACH restrictions for long chain perfluorocarboxylates.

18.6. Number of companies affected

18.6.1. 10,000+ companies

18.7. Annual Tonnage

18.7.1. 10 to 100 tons per annum.

18.8. Timeline Requested

18.8.1. 13.5 years - No suitable replacements and very low risk to human health (no forever chemicals).

19. C11 - PTFE coatings for cookware

19.1. Text for derogation

19.1.1. PTFE as a fused coating on cookware

19.2. Alternative text

19.2.1. n/a

19.3. Use and Functionality

19.3.1. PTFE has been used as a fused polymer coating on cookware metals for decades. These coatings are very different from the fluoroacrylate coatings on paper food contact packaging, which are based on side chain fluoropolymers weakly adhered to acrylic polymer backbones. Fused polymer coatings are pure PTFE powder heated and cured to the surface of the metal, without the weak / degradation bonds of fluoroacrylates.

19.3.2. Contrary to popular belief, PTFE on cookware

19.3.2.1. Does not contain forever chemicals (such as PFOA), and

19.3.2.2. Does not degrade into forever chemicals over time or at end-of-life.

19.3.3. PTFE has superior performance (low friction, hydrophobic, and oleophic) over all other polymers.

19.3.4. Ceramic coatings can achieve the same performance at a higher cost, but do not provide any chemical safety advantages. Ceramic coatings are also prosecuting in food contacting materials for heavy metals in California Proposition 65 very commonly (averaging over 10 prosecutions per month).

19.4. Substitutes / Alternatives

19.4.1. No other polymers have the same low friction, temperature resistance, hydrophobic and oleophobic properties, and chemical safety as PTFE fused coatings.

19.4.2. Ceramics have similar performance characteristics and provide chemical safety risks greater than fused PTFE coatings.

19.5. Forever Chemicals

19.5.1. None expected

19.5.2. Contrary to popular belief, fused PTFE coatings for cookware have not contained forever chemicals (PFOA family) for decades, and do not have a chemical structure that degrades into perfluorocarboxylates.

19.5.2.1. A good reference is “Determination of perfluorooctanoic acid (PFOA) extractable from the surface of commercial cookware under simulated cooking conditions by LC/MS/MS” 2005.

19.5.2.1.1. Claigan’s 2023 testing of cookware agreed with the results above (‘non detect’ for perfluorocarboxlates).

19.5.3. See Claigan Submission #3 - PFAS in Drinking Water for further explanation.

19.6. Number of companies affected

19.6.1. 10,000+ companies

19.7. Annual Tonnage

19.7.1. 10 to 100 tons per annum.

19.8. Timeline Requested

19.8.1. 13.5 years - No suitable replacements and very low risk to human health (no forever chemicals).

20. C11b - PTFE coatings for chemical containers

20.1. Text for derogation

20.1.1. PTFE as a coating for chemical containers

20.2. Alternative text

20.2.1. n/a

20.3. Use and Functionality

20.3.1. PTFE is an effective coating for chemical containers, whether portable or industrial.

20.3.2. PTFE is hydrophobic, oleophobic, acid resistant, alkali resistant, and maintains its characteristics over a wide temperature range. These properties are critical for chemical containers.

20.3.3. This derogation request is for PTFE coatings for containers or vessels that can hold chemical substances with safety or corrosion risks.

20.4. Substitutes / Alternatives

20.4.1. No other polymers have equivalent hydrophobic and oleophobic properties, and chemical safety over a range of temperatures as PTFE.

20.4.2. Ceramics have similar performance characteristics but could only be used to coat metal vessels. Ceramic coatings are more difficult to coat completely without gaps in larger containers, creating leakage or degradation risk.

20.5. Forever Chemicals

20.5.1. None expected. Unirradiated PTFE does not normally contain perfluorocarboxylates and does not further degrade into perfluorocarboxylates over time.

20.6. Number of companies affected

20.6.1. 100 - 1,000 companies

20.7. Annual Tonnage

20.7.1. 10 to 100 tons per annum.

20.8. Timeline Requested

20.8.1. 13.5 years - No suitable replacements, is a specialized use, replacement creates a safety risk, and is a very low risk to human health (no forever chemicals).

21. C12a - Fluoroelastomers for seals

21.1. Text for derogation

21.1.1. Fluoroelastomers (including perfluoroelastomers), fluorosilicone, and amorphous fluoro resins as a sealing material in situations requiring chemical resistance, oil resistance, oxidation resistance, decompression resistance, high temperature (over 150C), or low temperature (<-20C).

21.2. Alternative text

21.2.1. Fluoroelastomers - FKM (including perfluoroelastomers - FFKM), fluorosilicone, and amorphous fluoro resin as a sealing material.

21.3. Use and Functionality

21.3.1. Fluoroelastomers (and similar materials) are important chemical resistant sealing materials for environments requiring acid resistance, alkali resistance, water resistance, oil resistance, and/or high temperature performance.

21.3.2. Without sealing materials that can function in these harsh environments, there is a strong risk for equipment or product failure and shorter periods between required servicing..

21.3.3. Fluoroelastomer seals are used in a very wide range of applications including oil and gas, electronics, medical devices, laboratory equipment, and any other application that requires a rubber seal with strong temperature resistance.

21.3.4. Note 1 - fluoroelastomers are commonly called FKM from their ASTM standard, or by a common trade name of ‘Viton’.

21.3.5. Note 2 - perfluoroelastomers are commonly called FFKM from their ASTM standard, or by a common trade name of ‘Kalrez’.

21.4. Substitutes / Alternatives

21.4.1. No other rubbers have equivalent hydrophobic and oleophobic properties, oxidation resistance, and chemical safety over a range of low and high temperatures as fluoroelastomers. Fluoroelastomers are also very resistant to explosive decompression.

21.4.2. Fluoroelastomer use can extend product life/service intervals thereby reducing potential chemical releases/exposures. Alternative materials would need to be replaced monthly, as they begin to leak.

21.4.3. PTFE has similar environmental properties, but is a plastic and is not suitable for applications requiring the conformity of a ‘rubber’ seal. Fluoroelastomers also have a higher coefficient of friction than PTFE and create a superior ‘seal’ in most applications.

21.4.4. See Claigan PFAS Submission #4 - for a detailed list of specific performance advantages of fluoroelastomers, perfluoroelastomers, and fluorosilicones.

21.5. Forever Chemicals

21.5.1. Any approval of fluoroelastomers or perfluoroelastomers will need approval of 6:2 FTS fluorotelomer sulfonates (and substances that degrade into 6:2 FTS), and approval of a low concentration of short chain perfluorocarboxylates that degrade from 6:2 FTS (C4 to C7 perfluorocarboxylates). Additionally, approval will be required for low concentrations of residual bisphenol AF crosslinking additives.

21.5.2. A separate derogation for the necessary fluoroadditives from the manufacturing process of fluoroelastomers and perfluoroelastomers is included in a separate derogation request.

21.6. Number of companies affected

21.6.1. 10,000+ companies

21.7. Annual Tonnage

21.7.1. 10,000+ tons per annum.

21.8. Timeline Requested

21.8.1. 13.5 years - No suitable replacements, specialized uses, and replacement creates a safety risk.

22. C12b - Fluoroelastomers for seals in water and food contact

22.1. Text for derogation

22.1.1. Fluoroelastomers (including perfluoroelastomers), fluorosilicone, and amorphous fluoro resins as a sealing material for drinking water or food contact if compliant with EU drinking water directives and regulations.

22.2. Alternative text

22.2.1. N/A

22.3. Use and Functionality

22.3.1. Fluoroelastomers (and similar materials) are important chemical resistant sealing materials for drinking water equipment and food processing equipment.

22.3.2. Public, residential and industrial water supply systems are typically designed for long life (at least several decades) and access for maintenance and repair is limited. Components in particular have to meet high mechanical requirements such as sliding or sealing must function trouble-free for a long time without maintenance. The inherent stability of fluoropolymers also reliably prevents harmful substances from migrating into drinking water. Drinking water components are certified to ACS, DVGW and DWI (as well as others), which require testing for chemical substance migration and cytotoxic parameters as well as functionality within the product. Water treatment protects people and the environment every day. The known water treatment methods have proven to be energy efficient and reliable, but are directly dependent on the use of fluoropolymers. These are used, dismantled and disposed of by professional personnel.

22.3.3. The recast EU drinking water directive regulates the sum of PFAS in drinking water at 0.1 ug/L PFAS. This regulation would effectively restrict perfluorocarboxylates and perfluorosulfonates that could be present in fluoroelastomers.

22.4. Substitutes / Alternatives

22.4.1. No other rubbers have equivalent hydrophobic and oleophobic properties, UV resistance, and chemical safety over a range of temperatures as fluoroelastomers.

22.4.2. The most common alternatives are not chemically compatible for direct contact for long exposure time (years).

22.4.3. PTFE has similar environmental properties, but is a plastic and is not suitable for applications requiring the conformity of a ‘rubber’ seal. Fluoroelastomers also have a higher coefficient of friction than PTFE and create a superior ‘seal’ in most applications.

22.4.4. See Claigan PFAS Submission #4 - for a detailed list of specific performance advantages of fluoroelastomers, perfluoroelastomers, and fluorosilicones.

22.5. Forever Chemicals

22.5.1. None would be allowed. All applicable forever chemicals would be restricted under EU drinking water regulation.

22.5.2. The separate derogation request for 6:2 FTS, perfluorocarboxylates, and bisphenol AF would not be applicable to these materials if not in compliance with the PFAS restrictions of the recast EU drinking water regulation.

22.6. Number of companies affected

22.6.1. 100 to 1,000 companies

22.7. Annual Tonnage

22.7.1. 10 to 100 tons per annum.

22.8. Timeline Requested

22.8.1. 13.5 years - No suitable replacements, and hazardous PFAS strictly regulated in these materials by the recast EU drinking water regulation.

23. C13 - PTFE tape for sealing

23.1. Text for derogation

23.1.1. PTFE tape for moisture insulation, or joining of fluid or gas components. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates for 6.5 years

23.2. Alternative text

23.2.1. N/A

23.3. Use and Functionality

23.3.1. PTFE tape is one of the most commonly used sealing materials for fluid or gas components. PTFE tape is hydrophobic and oleophobic, providing strong resistance to any fluid or gas it is sealing against.

23.3.2. PTFE tape has more of a rubber-like property than standard PTFE and is useful in applications that require conforming and sealing uneven features (such as pipe threads).

23.3.3. PTFE tape is used in a wide range of consumer, professional, industrial, and medical applications requiring a seal from moisture (on an uneven surface), or joining of fluid or gas components.

23.3.4. PTFE tape is also used to reduce the friction between moving parts, but that application is different and is listed in a separate derogation.

23.4. Substitutes / Alternatives

23.4.1. No other tape materials have the same hydrophobic and oleophobic properties as PTFE tape.

23.5. Forever Chemicals

23.5.1. The majority of extruded PTFE tape contains a concentration of ~100 ppb of each of the perfluorocarboxylates (PFOA family). The source of perfluorocarboxylates in PTFE tape is not clear, but is present in the majority of PTFE tapes. The likely source is irradiation of the original PTFE powder to 'rubberize' the PTFE to make it easier to extrude and calender into tape. Irradiation of the initial powder would produce low concentrations of each perfluorocarboxylate chain length as fragments fracture by radiation from the original long polymer chain reacting with oxygen forming perfluorocarboxylates.

23.5.2. Extruded PTFE tape can be manufactured without perfluorocarboxylates, but it is so prevalent (even with the current EU POP and REACH restrictions for long chain perfluorocarboxylates) that it will take time to replace all of its uses in products.

23.5.2.1. To allow for the time it will take to identify which tapes contain perfluorocarboxylates, replace the materials, and requalify the products - a phase in period of 6.5 years is recommended for the complete removal of perfluorocarboxylate in PTFE tape.

23.5.2.2. Note - the cause of the generation of perfluorocarboxylates is related to the manufacturing process, and not expected to further increase with time as PTFE does not have a structure conducive to degradation into perfluorocarboxylates.

23.6. Number of companies affected

23.6.1. 10,000+ companies

23.7. Annual Tonnage

23.7.1. 100-1,000 tons per annum.

23.8. Timeline Requested

23.8.1. 13.5 years (PTFE Tape) - No suitable replacements, specialized uses, does not require forever chemicals, and replacement creates a safety risk.

23.8.2. 6.5 years (perfluorocarboxylates in PTFE tape up to 2 ppm) - The use of long chain fluorocarboxylated PTFE tape is very common in all levels of products and will take time to replace and requalify the products involved.

24. C13b - PTFE Tape for Friction Reduction

24.1. Text for derogation

24.1.1. PTFE tape for reduction of friction. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates for 6.5 years

24.2. Alternative text

24.2.1. N/A

24.3. Use and Functionality

24.3.1. PTFE tape is used to reduce friction between moving parts.

24.3.2. PTFE tape conforms easily to uneven surfaces and is needed for applications on imperfect surfaces. PTFE tape has more of a rubber-like property than standard PTFE and is useful in applications that require conforming and sealing uneven features.

24.3.3. PTFE tape for friction reduction is used in a wide range of consumer, professional, industrial, and medical applications requiring low friction between two or more components.

24.3.4. PTFE tape is also used to seal fluid and gas components, but that application is different and is listed in a separate derogation.

24.4. Substitutes / Alternatives

24.4.1. No other tape materials have as low friction as PTFE tape and the ability to conform to uneven surfaces.

24.4.2. Replacement of PTFE tape in a low friction application will affect product performance issues and reduced lifetime of the product - causing earlier disposal or replacement of the product using the PTFE tape.

24.5. Forever Chemicals

24.5.1. The majority of extruded PTFE tape contains a concentration of ~100 ppb of each of the perfluorocarboxylates (PFOA family). The source is not clear, but contained in the majority of PTFE tapes. The likely source is irradiation of the original PTFE powder to 'rubberize' the PTFE to make it easier to extrude and calender into tape. Irradiation of the initial powder

would produce low concentrations of each perfluorocarboxylate chain length as fragments fracture by radiation from the original long polymer chain react with oxygen forming perfluorocarboxylates.

24.5.2. Extruded PTFE tape can be manufactured without perfluorocarboxylates, but it is so prevalent (even with the current EU POP and REACH restrictions for long chain perfluorocarboxylates) that it will take time to replace all of its uses in products.

24.5.2.1. To allow for the time it will take to identify which tapes contain perfluorocarboxylates, replace the materials, and requalify the products - a phase in period of 6.5 years is recommended for the complete removal of perfluorocarboxylate in PTFE tape.

24.5.2.2. Note - the cause of the generation of perfluorocarboxylates is related to the manufacturing process, and not expected to further increase with time as PTFE does not have a structure conducive to degradation in to perfluorocarboxylates.

24.6. Number of companies affected

24.6.1. 1,000 - 10,000 companies

24.7. Annual Tonnage

24.7.1. 100-1,000 tons per annum.

24.8. Timeline Requested

24.8.1. 13.5 years (PTFE Tape) - No suitable replacements, specialized use, does not require forever chemicals, and replacement creates a product lifetime reduction.

24.8.2. 6.5 years (perfluorocarboxylates in PTFE tape up to 2 ppm) - The use of long chain fluorocarboxylated PTFE tape is very common in all levels of products and will take time to replace and requalify the products involved.

25. C14 - Fluorosilicone release paper

25.1. Text for derogation

25.1.1. Fluorosilcone release paper and residual fluorosilicone on adhesive products.

25.2. Alternative text

25.2.1. N/A

25.3. Use and Functionality

25.3.1. Fluorosilicone release paper is the most commonly used backing paper for stickers or similar materials.

25.3.2. This derogation includes fluorosilicone release paper and potential residue from the fluorosilicone release paper on the back of stickers (retention by the adhesive contacting the release paper).

25.3.3. Fluorosilicone has very low friction (and therefore adhesion) allowing stickers and other parts with adhesive to be placed on a roll or sheet to be peeled off for application.

25.3.4. Some fluorosilicone seems to remain adhered to the sticker adhesive, and is measurable above 100 ppm fluorine in the adhesive. As long as fluorosilicone release paper is allowed, it also needs to be allowed as a residual in the adhesive of stickers or similar parts such as silicone thermal pads in electronics.

25.3.4.1. Note - it is possible that, in some cases, the residual fluorine is from a fluorobased surfactant used to reduce the surface tension and improve the adhesion. Work is ongoing to separate the two uses as they look virtually identical with standard test methods.

25.4. Substitutes / Alternatives

25.4.1. Fluorosilicone release paper can be replaced by a number of materials including silicone (non-fluorinated) release paper, but fluorosilicone release paper is so common that it will take time for all the uses (in particular contamination of the adhesive of stickers) to be replaced.

25.5. Forever Chemicals

25.5.1. No fluorinated forever chemicals expected. Fluorosilicone does not normally contain perfluorocarboxylates and perfluorosulfonates, and do not have a structure expected to degrade into fluorinated forever chemicals over time.

25.5.2. The base silicone polymer is a risk for D4, D5, and D6 forever chemical like any siloxane based silicone rubber. Fluorosilicone release paper (and its

silicone replacement) are at risk of being regulated for residual D4, D5, and D6 forever chemicals.

25.6. Number of companies affected

25.6.1. 10,000+ companies

25.7. Annual Tonnage

25.7.1. 10 - 100 tons per annum.

25.8. Timeline Requested

25.8.1. 6.5 years - Can be replaced by other materials, but it will take time to replace all of its uses and its residual content in sticker adhesives for stickers that were originally on fluorosilicone release paper.

26. C16 - Fluorocoating of seals

26.1. Text for derogation

26.1.1. Fluorocoating of rubber, metal, and plastic seals in professional or industrial applications where chemical resistance or reduced friction is required

26.2. Alternative text

26.2.1. N/A

26.3. Use and Functionality

26.3.1. Standard rubber seals (of nitrile, silicone, or SBR rubber) or metal seals do not have the low friction properties or chemical resistance of PTFE.

26.3.2. Fluorocoating or encapsulation of rubber, such as nitrile rubber, provides chemical resistance to the rubber that the rubber does not normally possess and provides a reduced friction to the rubber.

26.3.3. Fluorocoating of metals provides a similar reduced friction and chemical resistance. For example, steel (even stainless steel) is vulnerable to acids and has very high friction. A fluorocoating protects the metal seals from environmental conditions.

26.3.4. Fluorocoated rubber is very common in medical and pharmaceutical applications including plungers / stoppers in syringes. Fluorocoated metal seals are rarer, but requirements in professional applications require acid resistance or other environmental resistance.

26.4. Substitutes / Alternatives

26.4.1. No other coating material provides the same environmental protection to rubber and metal seals.

26.5. Forever Chemicals

26.5.1. None expected. No fluorinated forever chemical above 25 ppb is expected in the coated.

26.6. Number of companies affected

26.6.1. 1,000-10,000 companies

26.7. Annual Tonnage

26.7.1. 10 - 100 tons per annum.

26.8. Timeline Requested

26.8.1. 13.5 years - No suitable replacements, specialized uses, and low risk to human health.

27. C17 - PTFE/PFA coating of metal for environmental resistance

27.1. Text for derogation

27.1.1. PTFE and PFA coating of metal for environmental or temperature resistance not in contact with food or drinking water

27.2. Alternative text

27.2.1. N/A

27.3. Use and Functionality

27.3.1. PTFE and PFA have excellent acid, alkali, water, and oil resistance. Many metals do not have good acid, water, or alkali resistance. PTFE or PFA coating of the metal improves the environmental resistance of the metal.

27.3.2. PTFE coatings are also used on metal parts in marine environments to protect against environmental (salt) and chemical corrosion. They can also reduce friction/power consumption, provide anti-galling properties, and other wear related issues.

27.3.3. Improved environmental resistance is needed for metals likely to be exposed to outdoor or chemical conditions (in particular at higher temperatures).

27.3.4. This derogation request is for uses not in contact with food or drinking water. Related coatings are handled under a separate derogation.

27.4. Substitutes / Alternatives

27.4.1. No other coating materials provide the same environmental protection to metals.

27.4.2. Replacement PTFE and PFA environmental coatings for metals will reduce the corrosion resistance (in particular over temperature) of many metals resulting in failure of these metals and/or reduced product lifetime (resulting in more products entering end of life disposal sooner).

27.5. Forever Chemicals

27.5.1. None expected in fused PTFE nor is PTFE expected to degrade into forever chemicals.

27.5.2. PFA often (but not always) contains perfluorocarboxylates and further degrades into perfluorocarboxylates (PFOA family). The presence and degradation potential is covered under a separate derogation request for perfluorocarboxylates in PFA.

27.6. Number of companies affected

27.6.1. 1,000-10,000 companies

27.7. Annual Tonnage

27.7.1. 10 - 100 tons per annum.

27.8. Timeline Requested

27.8.1. 13.5 years - No suitable replacements, specialized uses, does not include food or drinking water applications, and is low risk to human health.

27.8.1.1. Note - the potential for perfluorocarboxylates in PFA is addressed in another derogation request in this report and is unlikely to be needed in the long term.

28. C18 - Fluorocoating of metal for wear resistance

28.1. Text for derogation

28.1.1. PTFE, FEP, and PFA coating of metal for low friction and wear resistance in machinery or tools

28.2. Alternative text

28.2.1. N/A

28.3. Use and Functionality

28.3.1. Most metals have very high coefficients of frictions. Metal components in a potential friction situation with another metal have reduced functionality and greatly increased wear.

28.3.2. Examples include gears and shafts in machinery, but can involve any applications with moving metals parts.

28.3.3. Coating (as opposed to lubrication) of metal parts provides much longer (less temporary) wear resistance than lubrication alone.

28.4. Substitutes / Alternatives

28.4.1. No other coating materials provide equivalent reduced friction as PTFE or PFA for metals.

28.4.2. Replacement PTFE, FEP, and PFA environmental coatings will greatly reduce the performance of some machinery, increase wear, and reduce lifetimes on metal components.

28.4.3. Liquid lubricants can be used, but they are temporary in nature, and the most effective lubricants for low friction in metal parts contain PTFE powder and are covered by another derogation request.

28.5. Forever Chemicals

28.5.1. None expected in fused PTFE (or FEP) nor is PTFE (or FEP) expected to degrade into forever chemicals.

28.5.2. PFA often (but not always) contains perfluorocarboxylates and further degrades into perfluorocarboxylates (PFOA family). The presence and degradation potential is covered under a separate derogation request for perfluorocarboxylates in PFA.

28.6. Number of companies affected

28.6.1. 10,000+ companies

28.7. Annual Tonnage

28.7.1. 10 - 100 tons per annum.

28.8. Timeline Requested

28.8.1. 13.5 years - No suitable replacements, specialized uses, extends the lifetime of products, and is low risk to human health.

28.8.1.1. Note - the potential for perfluorocarboxylates in PFA is addressed in another derogation request in this report and is unlikely to be needed in the long term.

29. C19 - Fluoropolymers in hoses

29.1. Text for derogation

29.1.1. PTFE, PFA, FEP, and TFE copolymers in hoses in chemical, pump, or valve applications.

29.2. Alternative text

29.2.1. N/A

29.3. Use and Functionality

29.3.1. PTFE (and similar fluoropolymers such as PFA, FEP, and TFE copolymers) provide a wide range of chemical resistances to hoses (including braided hose) to transport chemicals.

29.3.1.1. This derogation request is for hoses and similar that require chemical resistance. Fluoropolymer tubing, which does not normally transport chemicals, is covered under a separate derogation request.

29.3.2. PTFE based polymers are acid resistant, alkali resistant, oil resistant, and can withstand high temperatures. In equipment that may have to transport corrosive or similar liquids (or gasses), PTFE related fluoropolymers provide the necessary functionality.

29.3.3. PTFE hoses have exceptional chemical compatibility, resistance to moisture and temperature, and handle high pressures.

29.3.4. Without PTFE based hoses, safe chemical handling in the EU will no longer be possible.

29.4. Substitutes / Alternatives

29.4.1. No other polymer that can be formed into hoses or braided to transport chemicals, or having the resistance to the same range of chemicals and temperatures.

29.4.2. See Claigan PFAS Submission #4 - Comparison of Alternatives - for a detailed list of specific performance advantages of PTFE based polymers over other potential polymers.

29.5. Forever Chemicals

29.5.1. None expected in unirradiated PTFE, FEP, or TFE based copolymers.

29.5.2. PFA often (but not always) contains perfluorocarboxylates and further degrades into perfluorocarboxylates (PFOA family). The presence and degradation potential is covered under a separate derogation request for perfluorocarboxylates in PFA.

29.6. Number of companies affected

29.6.1. 10,000+ companies

29.7. Annual Tonnage

29.7.1. 1,000+ tons per annum.

29.8. Timeline Requested

29.8.1. 13.5 years - No suitable replacements, specialized uses, and is necessary for the processing of chemicals in the EU.

29.8.1.1. Note - the potential for perfluorocarboxylates in PFA is addressed in another derogation request in this report and is unlikely to be needed in the long term.

30. C20 - Fluoropolymers in/on labels

30.1. Text for derogation

30.1.1. Fluorocoatings on labels of products (excluding textiles) necessary for environmental resistance.

30.2. Alternative text

30.2.1. N/A

30.3. Use and Functionality

30.3.1. Paper and polyester labels degrade in weather conditions such as rain, sun, or humidity.

30.3.2. By fluorocoating the surface of the label, the label can resist water, oil, and other environmental conditions. In many cases, these labels contain safety information that would create safety issues if subject to aging.

30.3.3. Fluorocoated labels are used in a wide range of applications including outdoor products, but can include an electronic product that requires the label to withstand humidity and high temperature (such as a hard drive).

30.4. Substitutes / Alternatives

30.4.1. Most polymers do not have the water resistance and oil/stain resistance of fluoropolymers.

30.4.1.1. PVC has nearly equivalent water and oil resistance, but has risks of other regulated substances (such as phthalates) and does not withstand temperature ranges as well as fluoropolymers.

30.5. Forever Chemicals

30.5.1. None expected.

30.5.1.1. This does not include fluoroacrylic coatings that would create perfluorocarboxylates (PFOA family) regulated under POP or REACH.

30.6. Number of companies affected

30.6.1. 10,000+ companies

30.7. Annual Tonnage

30.7.1. 10 - 100 tons per annum.

30.8. Timeline Requested

30.8.1. 13.5 years - No suitable replacements, require for safety warnings on products, and does not provide a risk to human health.

31. C21 - Fluoropolymers tubing

31.1. Text for derogation

31.1.1. PTFE, PFA, FEP, PVDF, ETFE, and fluoroelastomer (including perfluoroelastomer) tubing not intended for drinking water. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates

31.2. Alternative text

31.2.1. Two (2) derogations

31.2.1.1. PTFE, PFA, FEP, ETFE, and PVDF tubing not in contact with drinking water. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates

31.2.1.2. Fluoroelastomer tubing not in contact with drinking water.

31.2.2. Fluoroelastomers have a separate perfluorosulfonate risk from the irradiated PTFE/PVDF or PFA perfluoroalkyl carboxylate risk.

31.3. Use and Functionality

31.3.1. PTFE (and similar) tubing is used in a very wide range of applications either to transport fluid or to provide protection to another material.

31.3.2. PTFE tubing is common for fluid transportation in laboratory and medical equipment. Fluoropolymer tubing is non-reactive with virtually all fluids and does not affect the quality of the liquid or gas being transported.

31.3.3. Fluoropolymer tubing is widely used in electronics to protect wiring or other components. This tubing is not specifically wire insulation, but it is commonly used in tube or heat shrink form in applications requiring high temperature resistance. For example - the leads of most transformers in electronics are protected by PTFE tubes.

31.3.4. PTFE, PFA, FEP, ETFE, and PVDF are all used in tubing applications but each has a separate advantage for specific applications. PTFE is only for tubing with less flexibility requirements. PVDF is used in applications requiring a lower density than PTFE. PFA, FEP, ETFE, and fluoroelastomers are used in chemical environments specific to their performance advantages (PFA - flexibility and chemical resistance. FEP - complex shapes. ETFE - high tension applications. Fluoroelastomers - high flexibility environment).

31.4. Substitutes / Alternatives

31.4.1. No other polymer is as effective as a tubing material in applications in either

31.4.1.1. High temperature applications (electronics) or

31.4.1.2. Transportation of fluid and gasses (with no reactivity with the transported fluids).

31.4.2. Polyurethane and PVC tubing can be used in some applications, but have poor resistance to acids and bases, can release chemicals (isocyanates or phthalates) into the fluid, and have poor temperature stability.

31.5. Forever Chemicals

31.5.1. PTFE and PVDF tubing is often irradiated, in particular if used as heat shrink.

31.5.1.1. Irradiated PTFE and PVDF will contain a range of perfluorocarbooxylates up to a maximum of ~2 ppm C4-C14 perfluorocarboxylates. These perfluorocarboxylates are created during the irradiation process of the powder for the tubing and are not expected to further degrade into additional perfluorocarboxylates.

31.5.2. PFA often (but not always) contains perfluorocarboxylates because of its weak C-O-C side chain bond. The majority of PFA polymers (but not all as a shorter side chain will not produce the measurable perfluorocarboxylates) contain up to ~2 ppm perfluorocarboxylates.

31.5.3. Fluoroelastomers normally contain short chain fluorosalts such as 6:2 FTS and C4 to C7 perfluorocarboxylates. This is related to a necessary processing aid in their emulsion manufacturing process. The details are covered under a separate derogation request.

31.6. Number of companies affected

31.6.1. 10,000+ companies

31.7. Annual Tonnage

31.7.1. 100 to 1,000 tons per annum.

31.8. Timeline Requested

31.8.1. 13.5 years - No suitable replacements, required for fluid transport or temperature performance reasons, substitution would affect the majority of electronics on the EU market, and not in contact with drinking water.

32. C22 - Heat transfer fluids

32.1. Text for derogation

32.1.1. Heat transfer fluids for industrial applications

32.2. Alternative text

32.2.1. Heat transfer fluids for professional and industrial applications

32.3. Use and Functionality

32.3.1. Fluoro heat transfer liquids are used in a range of industrial applications to transport the heat from part of the machinery or equipment to another.

32.3.2. Fluoro heat transfer fluids are commonly used in semiconductor manufacturing, data centers, and in the military/aerospace industry.

32.3.3. These applications are very specialized with tremendous heat generation / transfer requirements.

32.4. Substitutes / Alternatives

32.4.1. No other fluids have equivalent heat capacity to transfer heat sufficiently in machinery. Replacement with other fluids would create safety and performance issues in industrial applications such as semiconductor manufacturing, data centers, and military/aerospace.

32.5. Forever Chemicals

32.5.1. None expected. Fluoro heat transfer fluids are commonly built on chemical structures of F, C, and N without the oxygen bonds that degrade into perfluorocarboxylates.

32.6. Number of companies affected

32.6.1. 100 to 1,000 companies

32.7. Annual Tonnage

32.7.1. 100 to 1,000 tons per annum.

32.8. Timeline Requested

32.8.1. 13.5 years - No suitable replacements, specialized industrial applications, low exposure to the public, and no expectation of forever chemicals.

33. C23a - PVDF and PTFE in batteries

33.1. Text for derogation

33.1.1. PVDF and PTFE as the cathode binder in lithium batteries

33.2. Alternative text

33.2.1. Fluoropolymers in lithium batteries

33.3. Use and Functionality

33.3.1. Fluoropolymers (primarily PVDF) are the standard binding agent in lithium batteries.

33.3.2. The cathode binder in lithium ion batteries is commonly PVDF and necessary for the functioning of high density lithium batteries.

33.3.3. Lithium batteries with fluoropolymer binders are used in virtually every lithium battery application from electric vehicles, to portable batteries, to medical and life safety devices.

33.4. Substitutes / Alternatives

33.4.1. No other polymer has the temperature resistance and chemical resistance of fluoropolymers. Other polymers could not maintain the rigorous performance requirements of a binder in a high density lithium battery.

33.4.2. Pb acid batteries have similar performance to lithium batteries, but can release Pb at the end of life and have a weight that makes them unusable for mobile applications including electrical vehicles.

33.5. Forever Chemicals

33.5.1. None expected. Unirradiated PVDF and PTFE does not contain perfluorocarboxylates and does have the C-O-C bond that leads to degradation of perfluorocarboxylates with time.

33.6. Number of companies affected

33.6.1. 10,000+ companies

33.7. Annual Tonnage

33.7.1. 1,000+ tons per annum.

33.8. Timeline Requested

33.8.1. 13.5 years - No suitable replacements, fundamental to mobile electronics, and necessary for electric vehicles.

34. C23b - Fluoropolymers in capacitors

34.1. Text for derogation

34.1.1. PVDF, PTFE, TFE, and sulfonated PTFE as a binder or spacer in capacitors

34.2. Alternative text

34.2.1. Fluoropolymers in capacitors

34.3. Use and Functionality

34.3.1. High performance capacitors, in particular ultra/super capacitors, require fluoropolymers as either a binder, or as an electric insulator in capacitors.

34.3.2. Fluorobinders in high performance capacitors enable the energy density required in compact / dense electronics.

34.3.3. Fluoropolymers have electric insulation performance that separates different elements of the capacitor.

34.3.4. Fluoropolymer binders and spacers are common in capacitors and are used in a wide range of electronic products.

34.4. Substitutes / Alternatives

34.4.1. No other polymer has the temperature resistance and dielectric insulation properties of fluoropolymers.

34.5. Forever Chemicals

34.5.1. None expected. Unirradiated PVDF and PTFE does not contain perfluorocarboxylates and does have the C-O-C bond that leads to degradation of perfluorocarboxylates with time.

34.6. Number of companies affected

34.6.1. 10,000+ companies

34.7. Annual Tonnage

34.7.1. 100 to 1,000 tons per annum.

34.8. Timeline Requested

34.8.1. 13.5 years - No suitable replacements, temperature and electrical insulation advantages over other materials, fundamental to electronics, and similar to the necessary fluoropolymers in lithium batteries.

35. C24 - Lubrication of internal wires

35.1. Text for derogation

35.1.1. PTFE and fluorosilicone lubricants for internal wires

35.2. Alternative text

35.2.1. Fluoro lubricants for internal wires

35.3. Use and Functionality

35.3.1. Hookwires inside cables are commonly lubricated with either a fluorosilicone or PTFE lubricant.

35.3.2. Lubrication of the internal wires reduces friction and wear of the cable, improving the flexibility and lifetime of the cable. Hookup wires inside cables have fluoro lubricants on their hook wires in roughly 25% of cables.

35.3.2.1. See Claigan PFAS Submission #1 - PFAS in Articles for further details.

35.3.3. The amount of lubricant on a wire is ~100 ppm fluorine.

35.3.4. Note - in some cases the fluoro lubricants on the hookup / internal wires are from fluoro lubricants on the manufacturing equipment and may not be present intentionally.

35.4. Substitutes / Alternatives

35.4.1. Fluoro lubricants, except in high temperature environments, are replaceable lubricants.

35.4.2. Note - in some cases the fluoro lubricants on the hookup / internal wires are from fluoro lubricants on the manufacturing equipment and may not be present intentionally.

35.5. Forever Chemicals

35.5.1. None expected. The trace amount of fluoro lubricant on a wire ~ 100 ppm and no forever chemicals would be measurably present in the wire.

35.6. Number of companies affected

35.6.1. 10,000+ companies

35.7. Annual Tonnage

35.7.1. 10 to 100 tons per annum.

35.8. Timeline Requested

35.8.1. 6.5 years - Substitutes are readily available but the use is so common (~25% of all cables) that it will take years to identify and replace all the occurrences.

36. C25 - Surfactant in assays

36.1. Text for derogation

36.1.1. Surfactants in emulsion based bio-assays and dry-chemistry assays

36.2. Alternative text

36.2.1. Surfactants in laboratory assays

36.3. Use and Functionality

36.3.1. Fluoro based surfactants are commonly used as the surfactants in specialized bio-assays and dry chemistry assays.

36.3.2. Fluoro based surfactants are useful for membrane protein stabilization in subsequent purification steps as they do not strip natural lipids and other co-factors from the proteins. In addition, the bulky fluorinated tails can not penetrate into the interior and disrupt structure. Fluorinated surfactants often decrease non-specific aggregation and are thought to result in improved distribution.

36.3.3. Without fluoro based surfactants, many specialized laboratory or medical measurements would not be possible or, at least, not with the same accuracy.

36.4. Substitutes / Alternatives

36.4.1. Replacement of fluoro-based surfactants would take years of research and validation, and - in many cases - not be possible.

36.5. Forever Chemicals

36.5.1. The fluorosurfactants would commonly degrade into perfluorocarboxylates or perfluorosulfonates, depending on their structure.

36.6. Number of companies affected

36.6.1. 10 to 100 companies

36.7. Annual Tonnage

36.7.1. 0 - 10 tons per annum.

36.8. Timeline Requested

36.8.1. 13.5 years - A very technical and highly specialized use. Replacement would take years of research and validation, and would likely reduce test performance and have little health advantage to society.

37. C26 - PTFE Coating of Rubber for Biotechnology

37.1. Text for derogation

37.1.1. PTFE foil coating of rubber for biotechnology or chromatography purposes

37.2. Alternative text

37.2.1. Fluoropolymer coatings for biotechnology or chromatography purposes

37.3. Use and Functionality

37.3.1. Fluorocoating of rubber for biotechnology or chromatography is common to provide the low reactivity / low friction of PTFE to rubber.

37.3.2. This application is similar in nature to fluorocoating of rubber seals for medical and pharmaceutical purposes, but this derogation request includes applications of rubber in biotechnology and chromatography beyond rubber seals.

37.3.3. Chromatography and biotechnology require low reactivity of materials, and a PTFE coating imparts chemical and resistance, and biocompatibility to silicone or nitrile rubber.

37.4. Substitutes / Alternatives

37.4.1. No other polymer has as low reactivity and low friction as PTFE. Specialized biotechnology or chromatography applications require the highest possible performance for measurement accuracy and consistency.

37.5. Forever Chemicals

37.5.1. None expected. Unirradiated PTFE does not contain perfluorocarboxylates (PFOA family) and is not expected to degrade over time into perfluorocarboxylates.

37.6. Number of companies affected

37.6.1. 10 to 100 companies

37.7. Annual Tonnage

37.7.1. 0 - 10 tons per annum.

37.8. Timeline Requested

37.8.1. 13.5 years - A very technical and highly specialized use. Replacement would take years of research and validation, and would likely reduce test performance and have little health advantage to society.

38. C27 - Products for Training or Simulation

38.1. Text for derogation

38.1.1. Products used for education or training purposes may use derogations applicable to products they are simulating.

38.2. Alternative text

38.2.1. N/A

38.3. Use and Functionality

38.3.1. Professional, medical, industrial, military, and aerospace applications often have simulators or other training aids to train or familiarize users with specific tasks.

38.3.2. The simulator or training aid may not be technically classified as a medical device or aerospace product, but it should be able to use any derogations available to the product it is simulating.

38.3.3. If a simulator or training aid is unable to use the same materials as the product it is simulating, gaps in design and training are possible. For example, an aircraft 'joystick' is made of PTFE, it would not make sense for the simulator's joystick to be made from another material because it does not benefit from a specific aircraft related derogation.

38.3.4. This is a very low volume but necessary usage.

38.4. Substitutes / Alternatives

38.4.1. The alternative is a different product design from the actual product from its simulator or training aid.

38.5. Forever Chemicals

38.5.1. None expected. Unirradiated PTFE does not contain perfluorocarboxylates (PFOA family) and is not expected to degrade over time into perfluorocarboxylates.

38.6. Number of companies affected

38.6.1. 10 to 100 companies

38.7. Annual Tonnage

38.7.1. 0 - 10 tons per annum.

38.8. Timeline Requested

38.8.1. 13.5 years - A very low volume usage that does not reasonably change the volume of fluorochemical for any application as the simulator or training aid would generally be expected to be much lower volume than the application or product it is simulating.

39. C28 - Fluorinated polyethylene for chemical storage

39.1. Text for derogation

39.1.1. Fluorinated polyethylene for chemical storage and handling. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates

39.2. Alternative text

39.2.1. Fluorinated polyethylene for chemical purposes. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates

39.3. Use and Functionality

39.3.1. Polyethylene is not resistant to all types of chemicals. In laboratory or chemical environments, fluorinated polyethylene is used for the storage of chemicals.

39.3.2. Fluorinated polyethylene is polyethylene that has been exposed to fluorine gas. The fluorine gas replaces some of the hydrogens in polyethylene creating a fluorinated polyethylene.

39.3.3. Fluorinated polyethylene is a chemical and UV resistance version of polyethylene and is widely used as a container or vessel for chemical storage or transport. Most laboratories or universities have some fluorinated polyethylene containers.

39.4. Substitutes / Alternatives

39.4.1. PFA fluoropolymer has similar performance as fluorinated polyethylene, but is more flexible and not suitable for most applications of fluorinated polyethylene.

39.4.1.1. PFA also often contains low concentrations of perfluorocarboxylates.

39.5. Forever Chemicals

39.5.1. Fluorinated polyethylene often contains a wide range of perfluorocarboxylates (PFOA family) due to the reaction of polyethylene and fluorine in an oxygen environment. Some of the polyethylene chains are fractured creating low concentrations of perfluorocarboxylates.

39.6. Number of companies affected

39.6.1. 100 to 1,000 companies

39.7. Annual Tonnage

39.7.1. 10 to 100 tons per annum.

39.8. Timeline Requested

39.8.1. 13.5 years - A very specialized usage with limited public exposure. Restricted to chemical handling and storage. Replacement would create a safety hazard for workers.

40. C29 - ePTFE seals

40.1. Text for derogation

40.1.1. ePTFE as a gasket / seal material in professional applications. Maximum of 5ppm of C4-C14 perfluoroalkyl carboxylates

40.2. Alternative text

40.2.1. ePTFE as a gasket / seal material. Maximum of 5ppm of C4-C14 perfluoroalkyl carboxylates

40.3. Use and Functionality

40.3.1. Expanded PTFE (ePTFE), like other fluoropolymers, is an excellent seal material for fluids.

40.3.2. ePTFE seals are listed as a separate derogation request as it commonly contains perfluorocarboxylates (PFOA family) and the derogation request is limited to professional uses.

40.3.3. At high and low temperatures such as industrial, commercial and even residential HVAC, refrigeration & cryogenic applications It is particularly

well suited for field service repairs due to its conformability and for applications requiring fast sealing/repeated use.

40.4. Substitutes / Alternatives

40.4.1. Other polymers do not have the chemical and temperature resistance or range of fluoropolymers.

40.4.2. ePTFE, unlike PTFE, is compressible and is useful for applications that require the performance of a fluoropolymer and compressibility.

40.5. Forever Chemicals

40.5.1. ePTFE commonly contains perfluorocarboxylates (PFOA family), likely from irradiation of the original powder to allow for expansion into a fibre. The perfluorocarboxylates are related to the manufacturing process, and ePTFE does not have the C-O-C bond that would lead to further degradation over time.

40.6. Number of companies affected

40.6.1. 100 to 1,000 companies

40.7. Annual Tonnage

40.7.1. 10 to 100 tons per annum.

40.8. Timeline Requested

40.8.1. 13.5 years - A specialized use for compressible fluoropolymer seals. Derogation requested is limited to professional applications that require specialized performance of ePTFE.

41. C31a - Fluoro acrylate side chain coatings for antismudge

41.1. Text for derogation

41.1.1. Fluoroacrylates for antismudge and antireflective coatings for plastics and glass. Maximum of 1ppm of C4-C6 perfluoroalkyl carboxylates.
Maximum of 1ppm of C7-C14 perfluoroalkyl carboxylates for 6.5 years

41.2. Alternative text

41.2.1. N/A

41.3. Use and Functionality

41.3.1. Side chain fluoropolymers are fluoropolymers such as fluorosilicone or fluoroacrylates that have a backbone of a non-fluorinated polymer (such as silicone or acrylic) with a side chain connected fluoro chain.

41.3.2. A side chain fluoropolymer bonds with a glass or plastic using its backbone chain of silicone or acrylic, and imparts fluoropolymer properties to the material with the side chain fluoro chain. These coatings are available in both standard and nano-coating form.

41.3.3. Side chain fluoropolymers are used as anti-smudge, anti-fingerprint, and anti-reflective coatings on surfaces.

41.3.4. This derogation request is only for fluoroacrylate and excludes fabric using fluoro side chain polymers for environmental or other uses.

41.3.5. Fluorosilicone and similar nano-coatings for the same purpose are covered in a separate derogation request.

41.4. Substitutes / Alternatives

41.4.1. Other anti-fingerprint coatings exist, such as parylene, but they do not adhere to plastic substrates as effectively as fluoropolymer side chain polymers and have lower thermal stability.

41.4.2. Fluoroacrlates are generally replaceable with non perfluorocarboxylate containing fluorosilicones or nanofluoropolymers.

41.5. Forever Chemicals

41.5.1. Fluoroacrylates contain a range of perfluorocarboxylates due to the weak C-O-C bond between the fluoro side chain and the base acrylic polymer. Fracturing of that bond during manufacturing and over time creates perfluorocarboxylates (PFOA family).

41.5.2. Fluorosilicones side chains are not attached to the base silicone polymer with weak C-O-C bonds, do not normally degrade into perfluorocarboxylates, and are covered under a separate derogation reqeust

41.5.3. Fluoro acrylate polymers are very commonly used, and a phase out is required.

41.6. Number of companies affected

41.6.1. 1,000 to 10,000 companies

41.7. Annual Tonnage

41.7.1. 10 to 100 tons per annum.

41.8. Timeline Requested

41.8.1. 6.5 years (long chain perfluorocarboxylates) - widely used but replaceable with nonperfluorocarboxylate (non-PFOA family) contains fluorosilicones and nanocoatings.

42. C31b - Fluorosilicone and nano fluoro coatings for antismudge

42.1. Text for derogation

42.1.1. Fluorosilicone and nano-fluorocoatings for antismudge and antireflective coatings for plastics and glass.

42.2. Alternative text

42.2.1. N/A

42.3. Use and Functionality

42.3.1. Side chain fluoropolymers are fluoropolymers such as fluorosilicone or fluoroacrylates that have a backbone of a non-fluorinated polymer (such as silicone or acrylic) with a side chain connected fluoro chain.

42.3.2. A side chain fluoropolymer bonds with a glass or plastic using its backbone chain of silicone or acrylic, and imparts fluoropolymer properties to the material with the side chain fluoro chain. These coatings are available in both standard and nano-coating form.

42.3.3. Side chain fluoropolymers are used as anti-smudge, anti-fingerprint, and anti-reflective coatings on surfaces.

42.3.4. This derogation request is only for fluorosilicone and nanofluorocoatings that do not contain perfluorocarboxylates (PFOA family) and do not degrade into perfluorocarboxylates.

42.3.5. Fluorosilicone and similar nano-coatings for the same purpose are covered in a separate derogation request.

42.4. Substitutes / Alternatives

42.4.1. Other anti-fingerprint coatings exist, such as parylene, but they do not adhere to plastic substrates as effectively as fluoropolymer side chain polymers and have lower thermal stability.

42.5. Forever Chemicals

42.5.1. Fluoroacrylates contain a range of perfluorocarboxylates due to the weak C-O-C bond between the fluoro side chain and the base acrylic polymer. Fracturing of that bond during manufacturing and over time creates perfluorocarboxylates (PFOA family).

42.5.2. Fluorosilicones side chains are not attached to the base silicone polymer with weak C-O-C bonds, do not normally degrade into perfluorocarboxylates, and are covered under a separate derogation reqeust

42.5.3. Fluoro acrylate polymers are very commonly used, and a phase out is required.

42.6. Number of companies affected

42.6.1. 1,000 to 10,000 companies

42.7. Annual Tonnage

42.7.1. 10 to 100 tons per annum.

42.8. Timeline Requested

42.8.1. 13.5 years - widely used, very low concentration, not easily replaceable with other materials, and no forever chemicals.

43. C32a - Fluoropolymer seals and spacers

43.1. Text for derogation

43.1.1. PTFE, FEP, PCTFE, PVDF, and TFE (including copolymers) as a sealing or spacer material.

43.2. Alternative text

43.2.1. N/A

43.3. Use and Functionality

43.3.1. PTFE (and similar) polymers are commonly used as sealing materials in products. PTFE seals are used in fluid applications, gas applications, and applications requiring protection from humidity.

43.3.2. PTFE seals are very common in fluid and gas components due to their acid resistance, alkali resistance, oil resistance, temperature resistance, and low weight. Virtually all fluid or gas transportation or storage equipment (consumer or professional) has at least one fluoropolymer seal.

43.3.3. PTFE seals are common in electronics for humidity protection. Moisture sensitive equipment with high operating temperature, such as hard drives, commonly use fluoropolymer seals for humidity protection.

43.3.4. In addition, PTFE seals extend product life/service intervals thereby reducing potential fluid and gas releases/exposures.

43.3.5. This derogation is intended to include PTFE as the main sealing material or as a reinforcement to another sealing material.

43.4. Substitutes / Alternatives

43.4.1. Other polymers do not have the wide range of environmental resistance as fluoropolymers and do not have the temperature resistance necessary for dense electronics.

43.4.2. In most applications, alternative sealing materials were tested, and no materials and closure systems showed positive results.

43.5. Forever Chemicals

43.5.1. None expected. Unirradiated PTFE, FEP, PCTFE, PVDF, and TFE copolymers do not perfluorocarboxylates and do not have the C-O-C bond that would lead to degradation into perfluorocarboxylates over time.

43.6. Number of companies affected

43.6.1. 10,000+ companies

43.7. Annual Tonnage

43.7.1. 100 to 1,000 tons per annum.

43.8. Timeline Requested

43.8.1. 13.5 years - Other polymers cannot meet the performance capability of fluoropolymer seals, replacement would introduce safety and performance risks to both fluid/gas applications and to electronics, replacement would reduce the life expectancy of electronics, and this usage has no expectation of perfluorocarboxylates being generated.

44. C32b - PFA seals

44.1. Text for derogation

44.1.1. PFA as a sealing or spacer material in professional applications.

44.2. Alternative text

44.2.1. PFA as a sealing or spacer material, or

44.2.2. Include PFA in the above PTFE (and similar) derogation

44.3. Use and Functionality

44.3.1. PFA seals are used in professional applications that require extreme chemical resistance or flexibility advantages not available with standard PTFE.

44.3.2. PFA seals are used in the food, chemical, and petrochemical industries in applications requiring resistance to cold-flow and compression or require an adaptive seal.

44.4. Substitutes / Alternatives

44.4.1. Other polymers do not have the wide range of environmental resistance as fluoropolymers and do not have temperature resistance necessary for dense electronics.

44.4.2. PTFE and similar fluoropolymers do not have the flexibility and adaptability of PFA.

44.5. Forever Chemicals

44.5.1. PFA commonly (but not always) has perfluorocarboxylates from fracturing of the side chain fluoro chain attached to the PFA fluoropolymer

44.5.2. A separate derogation request for perfluorocarboxylates is included in this report.

44.6. Number of companies affected

44.6.1. 100 to 1,000

44.7. Annual Tonnage

44.7.1. 10 to 1000 tons per annum.

44.8. Timeline Requested

44.8.1. 13.5 years - A specialized performance seal for professional/industrial uses. Replacement of PFA in specialized applications that require its chemical and temperature resistance with its adaptive properties (due to higher flexibility than other fluoropolymers) is not possible at this time.

45. C33 - PVDF and ETFE in circulation systems

45.1. Text for derogation

45.1.1. PVDF and ETFE as a component in fluid or gas systems

45.2. Alternative text

45.2.1. PVDF and ETFE as a component in fluid or gas systems for professional, industrial, medical, or pharmaceutical applications.

45.3. Use and Functionality

45.3.1. PVDF and ETFE are commonly used as a component in fluid or gas systems. PVDF is an excellent material for connectors in fluid systems. PVDF has advantages in high temperature tolerances that make it very useful for industrial or heating applications. ETFE has similar advantages to PVDF, but has high tensile strength.

45.3.2. PVDF and ETFE have excellent water, acid, alkali, and UV resistance and is commonly used for connectors, pipe fittings, flanges, pipes, and other components in fluid or gas systems.

45.3.3. The use of PVDF or ETFE in fluid or gas systems is related to (depending on the application) chemical resistance, temperature resistance, salt water resistance, UV resistance, tensile strength, and/or abrasion resistance.

45.4. Substitutes / Alternatives

45.4.1. The only other polymer with similar properties is PTFE. PTFE is higher density and has less abrasion resistance than PVDF. PVDF is preferred in

industrial or heating applications for piping. ETFE has higher tensile strength than PTFE and can be used under harsher conditions that PTFE.

45.5. Forever Chemicals

45.5.1. None expected. PVDF and ETFE does not normally contain any perfluorocarboxylates or perfluorosulfonates.

45.6. Number of companies affected

45.6.1. 10,000+

45.7. Annual Tonnage

45.7.1. 1,000+ tons per annum.

45.8. Timeline Requested

45.8.1. 13.5 years - No other polymers have the equivalent performance in fluid and gas applications, low risk to human health, and widely used.

46. C34 - PTFE for security protection of labels

46.1. Text for derogation

46.1.1. PTFE in coatings of labels for security or tamper evidence. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates.

46.2. Alternative text

46.2.1. PTFE in coatings of products for security or tamper evidence. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates

46.3. Use and Functionality

46.3.1. PTFE is used, not only as a label coating for environmental resistance, but also for security protection such as tamper evidence.

46.3.2. PTFE coating of a label or similar product protects the label from tampering. Removal of the PTFE is not achievable with simple chemicals and would require abrasion. The abrasion would easily show the tampering.

46.3.3. Unirradiated and irradiated PTFE is used in this application. Irradiated PTFE material film is also used in the label in order to provide evidence that the label seal has been damaged/broken by an “attacker”. The soft PTFE material is left on the product showing it to be "Void".

46.3.4. This is a relatively specialized low volume but necessary use of PTFE.

46.4. Substitutes / Alternatives

46.4.1. For security - no other polymer provides the same tamper proof properties (chemical resistance) as PTFE as a coating. Use of another polymer would reduce the security of devices especially those for financial transactions or personal identification.

46.4.2. For tamper evidence - PTFE material film (plus an adhesive) is used in the label in order to provide evidence. Other plastics do not have the combination of chemical resistance and visibility of tampering than irradiated (soft) PTFE.

46.5. Forever Chemicals

46.5.1. Unirradiated PTFE - None expected. PTFE coatings would not normally contain perfluorocarboxylates (PFOA family) and do not have the C-O-C bond that results in degradation into perfluorocarboxylates.

46.5.2. Irradiated PTFE - Irradiated PTFE normally contains a concentration of ~100 ppb of each of the perfluorocarboxylates (PFOA family). These perfluorocarboxylates are created during the original manufacturing process of the specialized security film. Since PTFE does not contain a fragile C-O-C bond, no further degradation is expected over time.

46.6. Number of companies affected

46.6.1. 10 to 100

46.7. Annual Tonnage

46.7.1. 0 to 10 tons

46.8. Timeline Requested

46.8.1. 13.5 years - Specialized low volume use, no reasonable alternatives, required for security and financial transactions, and limited risk to human health.

47. C35 - Fluoroacrylate and PFA coatings for semiconductors

47.1. Text for derogation

47.1.1. Fluoroacrylic coatings and PFA (and solvents) for encapsulation of capacitors or semiconductor components. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates and 10ppm residual fluoroethers

47.2. Alternative text

47.2.1. Fluoroacrylic coatings and PFA (and solvents) for capacitor and semiconductor manufacturing. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates and 10ppm residual fluoroethers

47.3. Use and Functionality

47.3.1. Thin fluoroacrylate coatings (often using fluoroether solvents) are commonly used for encapsulation / water protection of capacitors and semiconductors.

47.3.2. These very thin coatings on very small parts protect the capacitor or semiconductor device from water and other environmental contaminants, reducing the risk of failure and prolonging the lifetime of the device.

47.3.3. This application of fluoroacrylates or PFA is at very small concentrations and may not even be detectable by most laboratories test methods after application.

47.3.4. This derogation includes perfluoroethers used to manufacture the fluoroacrylate film. Perfluoroethers are a common solvent for fluoroacrylates.

47.4. Substitutes / Alternatives

47.4.1. No other thin coating provides the hydrophobic and oleophobic protection of fluoroacrylates while being able to adhere to acrylic and similar substrates.

47.5. Forever Chemicals

47.5.1. Fluoroacrylates and PFA normally contain perfluorocarboxylates from the fracturing of the C-O-C connecting the fluoro side chain to the acrylic or fluoro polymer backbone. However, the overall concentration of the fluoroacrylate or PFA coating on the device may be so small/thin, that the perfluorocarboxylates would not be measurable in the final device.

47.5.2. The application of fluoroacrylates on capacitors and semiconductors often requires a small amount of perfluoroethers as a solvent. A small concentration of perfluoroethers would be expected in the final coating, however the coating would be so small/thin that the fluoroethers would likely be not detectable with standard test methods.

47.6. Number of companies affected

47.6.1. 10,000+

47.7. Annual Tonnage

47.7.1. 0 to 10 tons

47.8. Timeline Requested

47.8.1. 13.5 years - Specialized use internal to electronics, very low human exposure, very low annual tonnage, reduces the potential for failure of electronic products, and prolongs the life of electronic devices.

48. C36 - Fluoro sprays for industrial lubrication

48.1. Text for derogation

48.1.1. PTFE and fluorosilicone sprays for maintaining lubrication in industrial equipment.

48.2. Alternative text

48.2.1. PTFE and fluorosilicone lubricants for maintaining lubrication in machinery.

48.3. Use and Functionality

48.3.1. Metal (and some plastic) parts have very high coefficients of frictions. PTFE and fluorosilicone sprays are capable of dramatically reducing the friction of metal parts with only a thin layer applied.

48.3.2. Fluorosprays are very commonly used on metal parts in contact with other metal parts such as gears, shafts, and bearings. Without a fluoro spray, the metal parts would have very high friction and wear.

48.3.3. Fluid lubrication is not possible in all situations, and a thin layer of PTFE or fluorosilicone is necessary for lubrication.

48.3.4. Note - one side effect of the use of fluorolubricants on machinery is that some of the lubricants can be expected (especially fluorosilicone) to migrate to products contacting machinery during their manufacturing process. Manufacturers will need to take care not to allow fluoro lubricants on their machinery to contaminate products they contact.

48.4. Substitutes / Alternatives

48.4.1. No other spray is as effective in low concentrations and thickness in achieving reducing friction.

48.4.2. Silicone spray is less effective than fluoro sprays and often contains D4, D5, and D6 forever chemicals (also regulated in the EU with further restriction expected). Silicone lubricants stay 'wet', apply thicker, do not have good high temperature resistance, and are less effective on moving parts.

48.4.3. Fluoroacrylates require specific plastic substances to adhere and normally contain perfluorocarbonxylates (and are not included in the scope of this derogation request).

48.5. Forever Chemicals

48.5.1. None expected. PTFE dry sprays and fluorosilicone sprays are not expected to have any measurable forever chemicals.

48.5.2. PTFE powder in dry spray is not expected to contain perfluorocarboxylates (PFOA) and does not contain the C-O-C bond that degrades into perfluorocarboxylates.

48.5.3. Fluorosilicone may contain trace amounts of D4, D5, and D6, but the thickness of the layer will normally reduce the concentration of those chemicals in the part below measurement detection.

48.6. Number of companies affected

48.6.1. 10,000+

48.7. Annual Tonnage

48.7.1. 100 to 1,000 tons

48.8. Timeline Requested

48.8.1. 13.5 years - Necessary for the proper functioning of machinery, low risk to human health, wide spread use, and no equivalent alternatives.

49. C37 - Fluoro ionic fluids in capacitors

49.1. Text for derogation

49.1.1. Ionic fluoro fluids as electrolytes in capacitors or batteries

49.2. Alternative text

49.2.1. Ionic fluoro fluids as electrolytes in electrical storage devices.

49.3. Use and Functionality

49.3.1. Ionic fluoro fluids (alternatively fluoro ionic fluids, or FILs) have a specialized use as electrolytes in capacitors and batteries.

49.3.2. FILs have chemical/biological inertness, easy recovery and recyclability, low surface tension, extreme surface activity, high gas solubility, negligible vapour pressure, null flammability, and high thermal stability.

49.3.3. FILs are used in lithium, sodium, magnesium, and zinc batteries as they are non-volatile, non-flammable, and high ionic conductivity.

49.3.4. FILs improve both the performance and safety of batteries and capacitors.

49.3.5. Note - Fluorohydrogenate ionic liquids, one of the most common FIL in capacitors, are very simply structures without a C-O-C and may be removed from the definition of PFAS in the future (as they generally only have one fully fluorinated carbon)

49.4. Substitutes / Alternatives

49.4.1. Other ionic fluids can be used, but these fluids do not exhibit either/or the performance or flammability resistance of FILs.

49.5. Forever Chemicals

49.5.1. None expected. FILs are a large range of chemicals, the commonly used FILs do not have a C-O-C bond that leads to degradation into perfluorocarboxylates (PFOA family).

49.5.2. This derogation request does not include a provision for perfluorocarboxylates, and any FIL that degrades into perfluorocarboxylates would be regulated under the long chain perfluorocarbonxylate restrictions of the EU POP and REACH Regulations.

49.6. Number of companies affected

49.6.1. 100 to 1,000 companies

49.7. Annual Tonnage

49.7.1. 10 to 100 tons

49.8. Timeline Requested

49.8.1. 13.5 years - Necessary for the safety and performance of high energy density capacitors and batteries, replacement would impact electric vehicles, and low risk to human health.

50. C38 - PFPE lubricants for harsh environments

50.1. Text for derogation

50.1.1. Perfluorinated polyether (PFPE) as a lubricant for harsh environments

50.2. Alternative text

50.2.1. Perfluorinated polyether (PFPE) as a lubricant in professional and industrial applications.

50.3. Use and Functionality

50.3.1. Perfluorinated polyethers (PFPE) are used in harsh environments requiring high reliability.

50.3.2. PFPE operates effectively between -70C and 300C, does not exhibit oxidation, and has low losses from evaporation. PFPE enables longer relubrication intervals and may be suitable for the lifetime of the application.

50.3.3. PFPE's low evaporation losses make it suitable for high and ultra vacuum environments.

50.3.4. Harsh environments can include high temperature, corrosive, solvent, natural gas, high vacuum, or equivalent hard environments.

50.4. Substitutes / Alternatives

50.4.1. Silicone oil does not have the temperature range of PFPE and is not suitable for contact with some plastics. PFPE can handle a higher temperature range and is compatible with a wider range of rubbers.

50.5. Forever Chemicals

50.5.1. None expected. PFPE can theoretically degrade into C3 or shorter perfluorocarboxylates, but there is no record of that situation being measured in practice. Note - Standard testing for perfluorocarboxylates is for C4 perfluorocarbxylates and longer.

50.6. Number of companies affected

50.6.1. 100 to 1,000 companies

50.7. Annual Tonnage

50.7.1. 10 to 100 tons

50.8. Timeline Requested

50.8.1. 13.5 years - No equivalent replacement and intended for harsh environments with very limited human exposure such as machinery in a vacuum.

51. C40 - Pefluorocarboxylates in PFA

51.1. Text for derogation

51.1.1. Maximum of 5ppm of C4-C14 perfluoroalkyl carboxylates in derogated applications of perfluoroalkoxy alkane (PFA)

51.2. Alternative text

51.2.1. C4-C14 perfluoroalkyl carboxylates in derogated applications of perfluoroalkoxy alkane (PFA).

51.3. Use and Functionality

51.3.1. This derogation request is for perfluorocarboxylates in approved derogations of PFA.

51.3.2. Perfluoroalkoxy alkane (PFA) polymers have C-O-C connected fluoro side chains. These C-O-C bonds break during manufacturing and further degrade over time creating perfluorocarboxylates.

51.3.3. The length of the side chain does vary amongst different PFA. For very short side chains (single fully fluorinated carbons), measurable

perfluorocarboxylates are not created. For PFA polymers with longer side chains, a range of short and long chain perfluorocarboxylates are created.

51.3.4. The majority of tested PFA materials in articles measured ~100 ppb of each of C4 to C14 perfluorocarboxylates (PFOA family). But not all tested PFA contained perfluorocarboxylates.

51.4. Substitutes / Alternatives

51.4.1. PFA commonly has perfluorocarboxylates but does not have to. It will take time to identify and replace perfluorocarboxylate forming PFA as both perfluorocarboxylate containing and non-containing PFA are described as the same polymer and PFA is very widely used in many industries (consumer, professional, medical, and industrial).

51.5. Forever Chemicals

51.5.1. PFA have fluorinated side chains connected by a C-O-C bond. Those side chains can degrade into perfluorocarboxylates through cleavage of the C-O-C bond.

51.5.2. A separate derogation request for perfluorocarboxylates in PFA polymers is included in this report.

51.6. Number of companies affected

51.6.1. 10,000+ companies

51.7. Annual Tonnage

51.7.1. 0 to 10 tons (perfluorocarboxylates. Likely <1 tonne per annum)

51.8. Timeline Requested

51.8.1. 6.5 years - Perfluorcarboxylates are in the majority of PFA polymers but are not required for PFA polymers. However, perfluorocarboxylates are common in the majority of PFA polymers and it will take time to identify and replace perfluorocarboxylates containing PFA with non-perfluorocarboxylate containing PFA.

52. C41 - Perfluorosulfonates in Fluoroelastomers

52.1. Text for derogation

52.1.1. Maximum of 10 ppm 6:2 FTS, 5ppm C4-C6 perfluoroalkyl carboxylates, and 10 ppm bisphenol AF in derogated applications of fluoroelastomers and perfluoroelastomers

52.2. Alternative text

52.2.1. 6:2 FTS, C4-C6 perfluoroalkyl carboxylates, and bisphenol AF in derogated applications of fluoroelastomers and perfluoroelastomers

52.3. Use and Functionality

52.3.1. This derogation request is for perfluorosulfonates, perfluorocarboxylates, and bisphenol AF crosslinker in approved derogations of fluoroelastomers (including perfluoroelastomers).

52.3.2. The manufacturing process for fluoroelastomers used a C6 (6 carbon fluorine chain) based fluorotelomer sulfonate surfactant for emulsion polymerization. The surfactant degrades into 6:2 fluorotelomer sulfonate (6:2 FTS - a short chain fluorotelomer sulfonate). Over time 6:2 FTS degrades into C4-C7 perfluorocarboxylates (short chain members of the PFOA family). Any approved derogation for fluoroelastomers would need a derogation for the degradation products of the surfactant for manufacturer fluoroelastomers.

52.3.3. Fluoroelastomers are crosslinked rubber that commonly use bisphenol AF as the crosslinker. Any approved derogation for fluoroelastomers would need a derogation for residual bisphenol AF.

52.4. Substitutes / Alternatives

52.4.1. There are currently no alternatives for the fluorotelomer sulfonate surfactants used for emulsion polymerization of fluoroelastomers. The principal manufacturers of fluoroelastomers are researching alternatives but there is currently no reasonably feasible alternative.

52.5. Forever Chemicals

52.5.1. 6:2 FTS and C4-C7 perfluorocarboxylates as degradation products of the fluorotelomer sulfonate surfactant manufacturing aid.

52.5.2. Residual bisphenol AF as the crosslinking agent.

52.6. Number of companies affected

52.6.1. 10,000+ companies

52.7. Annual Tonnage

52.7.1. 0 to 10 tons (perfluorocarboxylates and perfluorosulfonates. Likely <1 tonne per annum)

52.8. Timeline Requested

52.8.1. 13.5 years - No current replacements for the emulsion surfactant and crosslinkers for fluoroelastomers. Fluoroelastomers have specialized uses and derogation of the degradation products of their manufacturing aids is needed for their continued use.

53. C43 - PVDF in ferroelectric films

53.1. Text for derogation

53.1.1. PVDF polymers and PVDF terpolymers for ferroelectric films.

53.2. Alternative text

53.2.1. PVDF polymers and PVDF terpolymers for ferroelectric films in actuators and micro sensors.

53.3. Use and Functionality

53.3.1. PVDF based polymers (PVDF polymers and PVDF terpolymers) are used for ferroelectric films in actuators and micro sensors.

53.3.2. PVDF films have ferroelectric and piezoelectric properties that make them very useful for actuators and micro sensors.

53.3.3. PVDF films have the advantages of a stable molecular dipole moment, compact crystal structure, conformational flexibility, and minimal steric hindrance. Ferroelectric polymers, either PVDF or P(VDF-TrFE), have large piezoelectric coefficients and high electrical outputs.

53.4. Substitutes / Alternatives

53.4.1. Specialized PVDF films have the highest dielectric constant of polymers, are new innovations, and are not replaceable with other materials.

53.5. Forever Chemicals

53.5.1. None expected. PVDF and PVDF terpolymers do not contain perfluorocarboxlates and do not have a chemical structure conducive to degradation into perfluorocarboxylates.

53.6. Number of companies affected

53.6.1. 10 to 100 companies

53.7. Annual Tonnage

53.7.1. 0 to 10 tons

53.8. Timeline Requested

53.8.1. 13.5 years - Very specialized low volume use with little risk to human health.

54. C44 - Fluoroether for degreasing applications

54.1. Text for derogation

54.1.1. Fluoroethers for degreasing applications

54.2. Alternative text

54.2.1. N/A

54.3. Use and Functionality

54.3.1. Fluoroethers for vapour solvent degreasing of machined parts is widely used.

54.3.2. Fluoroethers have high solvency strength, low nonvolatile residue and low surface tension. Fluorinated solvents provide excellent cleaning performance.

54.3.3. Fluoroethers are critical for comprehensive cleaning of metal machined parts particularly for the medical and pharmaceutical industries.

54.3.4. Without fluorethers, residue and contamination on machine parts will be common on machined parts.

54.4. Substitutes / Alternatives

54.4.1. Chlorinated and brominated solvents can be used to degrease metal parts, they have higher greenhouse gas and environmental emissions; and reduced solvency power - resulting in most environmental hazards and would reduce part quality.

54.5. Forever Chemicals

54.5.1. None expected. Fluoroethers are not expected to degrade into perfluorocarboxylates. Fluoroethers themselves have short half lifes in the environment and are not bioaccumulants of their own.

54.6. Number of companies affected

54.6.1. 1,000 to 10,000 companies

54.7. Annual Tonnage

54.7.1. 100 to 1,000 tons

54.8. Timeline Requested

54.8.1. 13.5 years - Necessary for reduced greenhouse gas emissions, reduced contaminants on medical devices, degrade in the environment, and have low risk to human health.

55. C45 - HFO for Insulating Foam

55.1. Text for derogation

55.1.1. Hydrofluoroolefins used as blowing agents for insulating spray foam internal to products.

55.2. Alternative text

55.2.1. Hydrofluoroolefins used as blowing agents for spray foam.

55.3. Use and Functionality

55.3.1. Hydrofluorolefins (HFO) are a low greenhouse gas blowing agent for insulating foam.

55.3.2. HFO blowing agents are not flammable, have zero ozone depletion potential (ODP), and have low global warming potential (GWP).

55.3.3. HFOs are technicallyc2 PFAS, but most only have one fully fluorinated carbon and may not qualify as a PFAS in update definitions that require chains for at least two fully fluorinated carbons.

55.4. Substitutes / Alternatives

55.4.1. HFOs are the environmentally friendly replacements for hydrofluorocarbons (HFCs). To meet greenhouse gas emissions targets, companies need to continue to use and convert to HFOs.

55.5. Forever Chemicals

55.5.1. None expected. HFOs do not have C-O-C bonds that lead to degradation into perfluorocarboxylates.

55.6. Number of companies affected

55.6.1. 10 to 100 companies

55.7. Annual Tonnage

55.7.1. 100 to 1,000 tons

55.8. Timeline Requested

55.8.1. 13.5 years - Necessary for reducing greenhouse gasses, and no expected risk to human health.

56. C46 - PTFE as a high temperature manufacturing aid or tool

56.1. Text for derogation

56.1.1. PTFE as a manufacturing aid or tool for high temperature (> 150C) applications

56.2. Alternative text

56.2.1. N/A

56.3. Use and Functionality

56.3.1. PTFE has high temperature tolerance and is commonly used in manufacturing processes as a tool or aid.

56.3.2. Numerous manufacturing processes involve high temperatures (such as soldering) and PTFE is commonly used as a holder or tool for the process.

56.3.3. Examples of PTFE as a high temperature manufacturing aid is a holder for parts during soldering, cutting jig, or insertion tool. Many of the applications covered in this derogation are custom and specialized for a specific manufacturing process.

56.4. Substitutes / Alternatives

56.4.1. Metals are too thermally conductive for most high temperature manufacturing processes. Other polymers either do not have the temperature resistance of PTFE (example - polyethylene) or are difficult to machine into custom tools (example - PEEK).

56.5. Forever Chemicals

56.5.1. None expected. Unirradiated PTFE does not contain perfluorocarboxylates and does not have C-O-C bonds that lead to degradation into perfluorocarboxylates.

56.6. Number of companies affected

56.6.1. 1,000 to 10,000 companies

56.7. Annual Tonnage

56.7.1. 1,000 - 10,000 tons

56.8. Timeline Requested

56.8.1. 13.5 years - Alternative materials do not have the necessary high temperature resistance and machinability, this derogation is limited to professional applications, and no expected risk to human health.

57. C48 - Fluorocoatings for optical components

57.1. Text for derogation

57.1.1. Fluorocoatings on laser fibers, laser fiber components, and fibers for optical purposes including light guidance.

57.2. Alternative text

57.2.1. N/A

57.3. Use and Functionality

57.3.1. Optical fibers and optical fiber based components commonly use fluoroacrylate coatings for guiding light for use in industrial, medical, defense, instrumentation, telecommunication and sensing markets.

57.3.2. UV curable coatings based on fluorinated polymers (amorphous fluoropolymers) are used in the connecting optical fibres or fiber based components to maintain light guidance along a chain of fiber and fiber based compoonents making a device.

57.3.3. For optical components, light guidance needs to be maintained with high reliability and precise optical matching to avoid losses and transmit light between beam forming between components.

57.3.4. These applications generally require fluoropolymers coating applied to glass typically in tens of micrometer thickness to accept and deliver high numerical aperture light.

57.3.5. This derogation includes both the fluorocoating and potential residual perfluoroethers solvents that may be present in the final film.

57.4. Substitutes / Alternatives

57.4.1. Alternative materials are not as transparent to visible light and have poorer optical matching properties.

57.5. Forever Chemicals

57.5.1. None expected. The amount of amorphous fluoropolymer is not sufficient for measurable perfluorocarboxylates in the final device even for a potential degradation product.

57.6. Number of companies affected

57.6.1. 100 to 1,000

57.7. Annual Tonnage

57.7.1. 0 to 10 tons

57.8. Timeline Requested

57.8.1. 13.5 years - Alternative materials do not have same performance / light compatibility, no expected risk to human health, and is a low volume application.

58. C51 - F2 gas fluorinated plastics in capacitors

58.1. Text for derogation

58.1.1. F2 gas fluorinated plastics in capacitors and microchips

58.2. Alternative text

58.2.1. N/A

58.3. Use and Functionality

58.3.1. A microlayer of fluorinated material is created in capacitors and semiconductor devices by F2 gas fluorination (usually plasma fluorination) of a plastic such as polyethylene or polyphenylene sulfide

58.3.2. The thin layer has amorphous fluorinated alkane molecules.

58.3.3. This very thin internal fluorinated layer provides specialized capacitance curves and is useful in specialized applications.

58.4. Substitutes / Alternatives

58.4.1. Thin fluorinated plastics provide capacitance performance advantages not available in other materials.

58.5. Forever Chemicals

58.5.1. None expected. The fluorination occurs mostly in argon and is not expected to create the perfluorocarboxylates generally seen in fluorination of plastics in air.

58.6. Number of companies affected

58.6.1. 100 to 1,000

58.7. Annual Tonnage

58.7.1. 0 to 10 tons

58.8. Timeline Requested

58.8.1. 13.5 years - Alternative materials do not have the same performance, no expected risk to human health, internal to electronics, and is a low volume application.

59. C52 - PTFE additive in die attach paste

59.1. Text for derogation

59.1.1. PTFE filled die attach material for semiconductor devices

59.2. Alternative text

59.2.1. N/A

59.3. Use and Functionality

59.3.1. PTFE added to die attach paste in semiconductor component for improved thermal performance.

59.3.2. The additive of PTFE to the die attach paste reduces ‘popcorning’ for repeat solder re-flows of the component.

59.4. Substitutes / Alternatives

59.4.1. No other polymer powder is as chemically inert and have as high temperature resistance as PTFE powder.

59.5. Forever Chemicals

59.5.1. None expected. Unirradiated PTFE does not contain perfluorocarboxylates and is not expected to degrade into perfluorocarboxylates.

59.6. Number of companies affected

59.6.1. 1,000 to 10,000

59.7. Annual Tonnage

59.7.1. 0 to 10 tons

59.8. Timeline Requested

59.8.1. 13.5 years - Alternative materials do not have the same performance, no expected risk to human health, internal to electronics, and is a low volume application.