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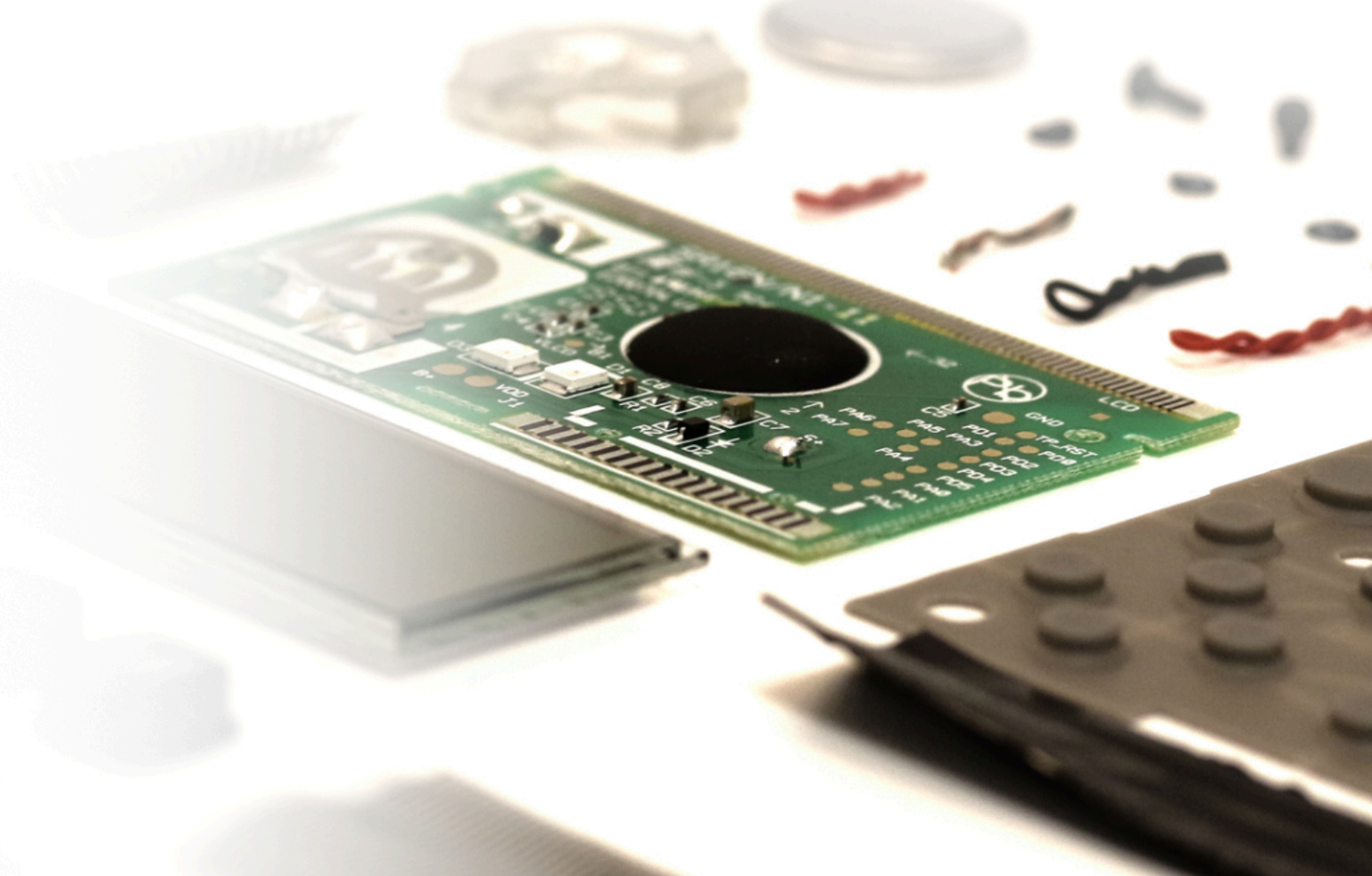
Less Journey. More Results.

Claigan Webinar

New Restricted Substances - 2022

Presented by:
Bruce Calder
VP Consulting Services at Claigan

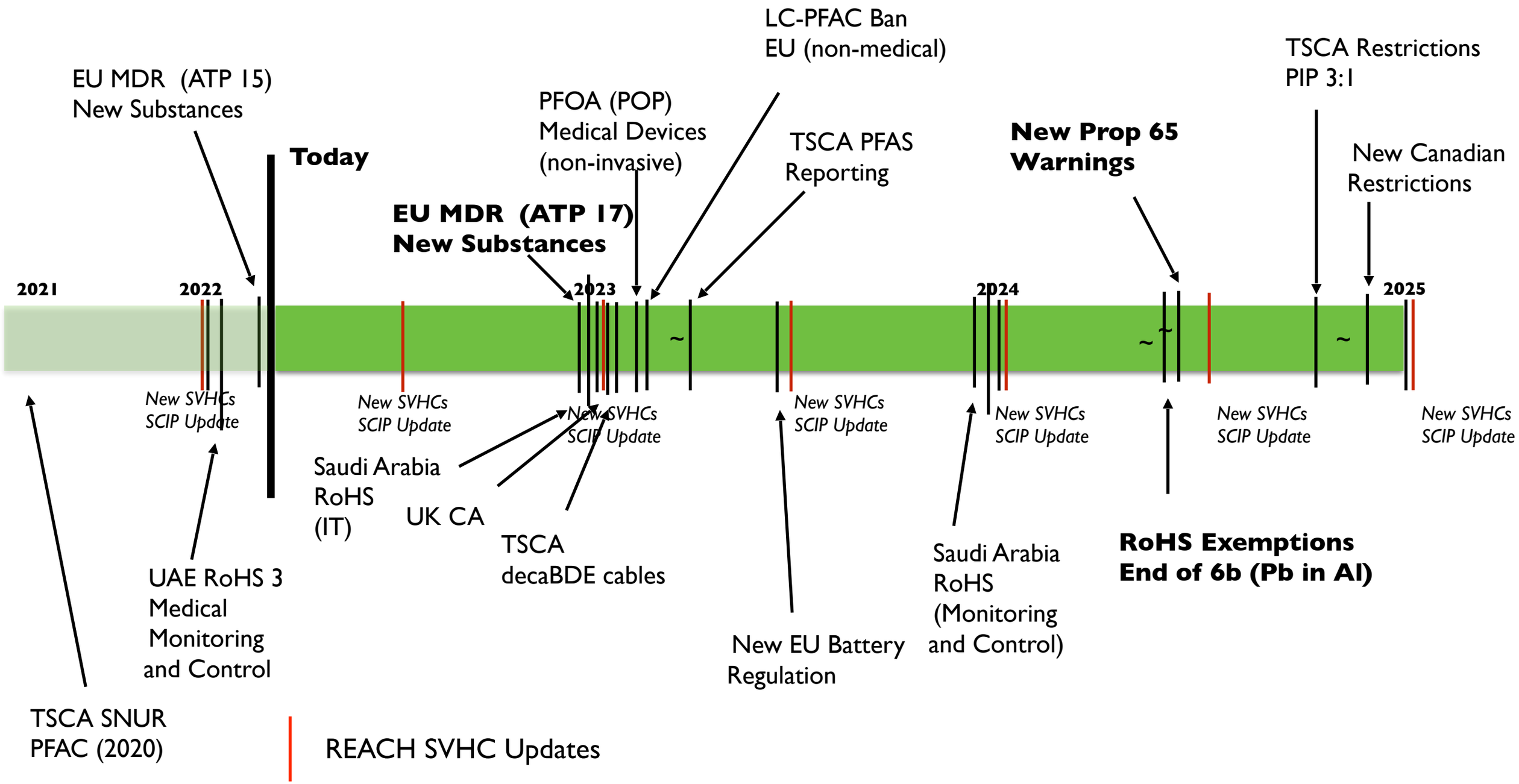
April 27 2022



Overview - Agenda

- Upcoming deadlines
- Claigan Services
- REACH SVHC
  - January 2022 Update
- EU MDR
  - ATP 15
  - ATP 17
  - Ethylene Oxide (EtO)
- REACH Restrictions
  - Long chain perfluoroalkyl carboxylates (LC-PFAC)
- New POP Substance
- Q&A

Restricted Materials
Constant Deadlines



… not to mention REACH SVHC updates every six months and Prop 65 every year.

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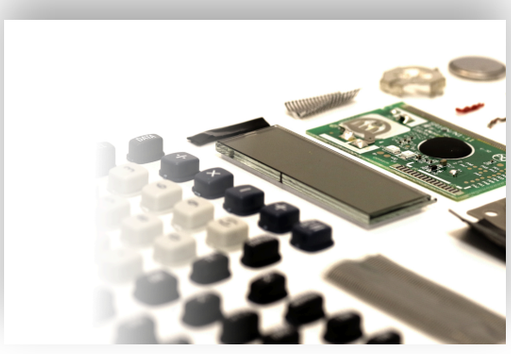
- Laboratory testing
  - For all global restricted materials regulation
    - /w version identification for regulation and list change
  - Testing 10,000s of products

- Regulatory
  - Quarterly updates (web educational)
  - Risk assessments
  - Opinions



Risk Assessments

- Substance Risk Assessments
- Included in Quarterly Update Service

Claigan Environmental Inc.
10 Brewer Hunt Way, Suite 200
Kanata, ON, Canada, K2K 2B5

EU MDR - 17th Adaptation to Technical Progress + EDC Update

Risk assessment of potential presence in EU medical devices for new substances identified as category 1 carcinogens, mutagens, or reproductive toxins (CMR) under the **17th Adaptation to Technical Progress**[1] and have been classified under REACH SVHC as Endocrine Disrupting Chemicals (EDC)[2] since the previous ATP update.

ATP 17 - Added

Substance	Risk	Justification	Materials of Risk
boric acid	Low risk	Not in soluble form in final product. Previous CMR 1. But previously with a concentration limit that made it out of scope. Risk assessment here is for 0.1% w/w. REACH SVHC (2010).	N/A
diboron trioxide	Low risk	Ingredient of borosilicate glass. Not in the form of diboron trioxide in final product. But	N/A

Risk Assessments

- REACH SVHC, REACH Restrictions, Prop 65, POP, EU MDR, and more…..

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January 17, 2022 Addition of SVHCs

Risk assessment of potential presence in physical products (articles) of the four (4) REACH SVHC substances added to the EU Candidate List for Authorisation on January 17, 2022 (223 substances).

Substance	Risk	Justification	Materials of Risk
tris(2-methoxyethoxy)vinylsilane	Low risk	Monomer for adhesion of mineral filled polymers. Will be well below 0.1% as a trace monomer in final article	N/A
S-(tricyclo(5.2.1.0'2,6)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate	Low risk	High performance lubricant additive	N/A
4-MBC	Low risk	UV filter for human sunscreen	N/A
6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	High risk	Two uses - a) cyano acrylate - ~0.2% of final adhesive. Unlikely to be above	Transparent or light coloured vulcanized

New REACH SVHCs

1. Tris(2-methoxyethoxy)vinylsilane
   - *Monomer for adhesion of mineral-filled polymers*

2. 6,6’-di-tert-butyl-2,2'-methylenedi-p-cresol (dbmc)
   - *Anti-oxidant in light coloured polymers*

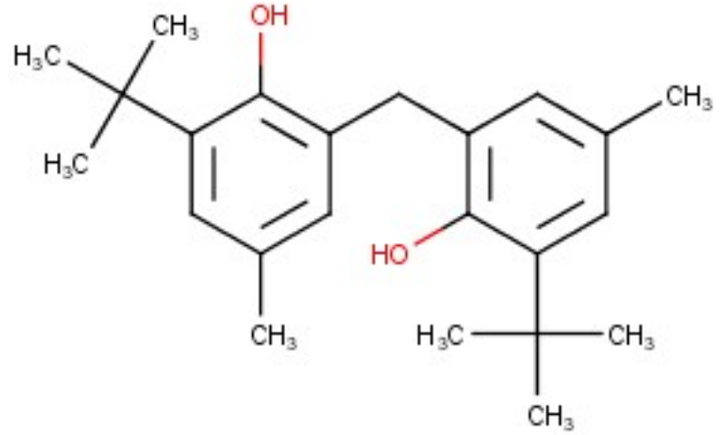
3. S-(tricyclo(5.2.1.0'2,6)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate
   - *High performance lubricant additive*

4. 4-MBC
   - *Regulated UV filter ingredient for sunscreen*

6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol

- **Details**
  - 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol
    - EC # 204-327-1
    - dbmc (short name)
  - Suspected reproductive toxin
- **Uses**
  - Anti-oxidant
  - Very common in 'super glues'
    - Cyano acrylates (loctite) *(low risk)*
  - Antioxidant in light coloured
    - Vulcanized rubber

Unclear RISK of Presence >0.1% w/w in Light coloured vulcanized Rubber



New Proposition 65 Substances

- Listed at end of December 2021
  - In effect December 2022

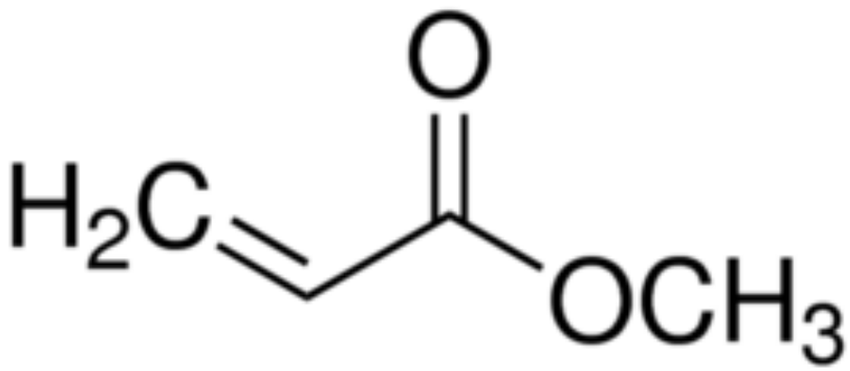
- Substances
  - Tetrahydrofuran
  - 2-Ethylhexyl acrylate
  - Methyl acrylate
  - Trimethylolpropane triacrylate, technical grade
  - PFOS
  - PFNA

US (California) - Proposition 65 - New Listings

- **Details**
  - Methyl acrylate (CAS RN 96-33-3)

Low Risk unless wearable / invasive acrylic

- **Uses**
  - Comonomer
    - acrylic fibre
    - thermoplastic coating
    - adhesives
    - sealants
    - **acrylics**
      - PMMA (ie. plexiglass)
      - Replacement for polycarbonate
      - trace residual after polymerization

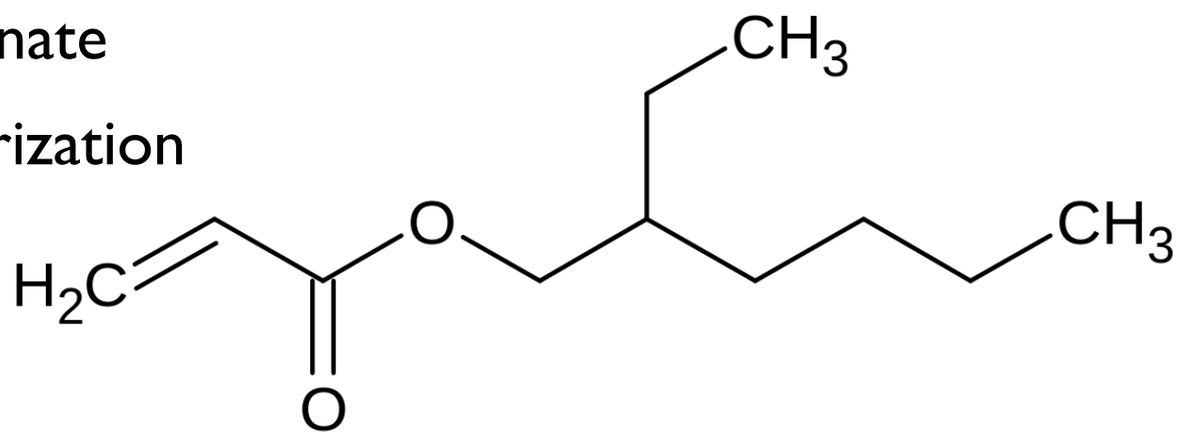


US (California) - Proposition 65 - New Listings

- **Details**
  - 2-Ethylhexyl acrylate (CAS RN 103-11-7)

Low Risk unless wearable / invasive acrylic

- **Uses**
  - monomer
    - adhesives
    - industrial coatings
    - paints
    - **acrylics**
      - PMMA (ie. plexiglass)
      - Replacement for polycarbonate
      - trace residual after polymerization

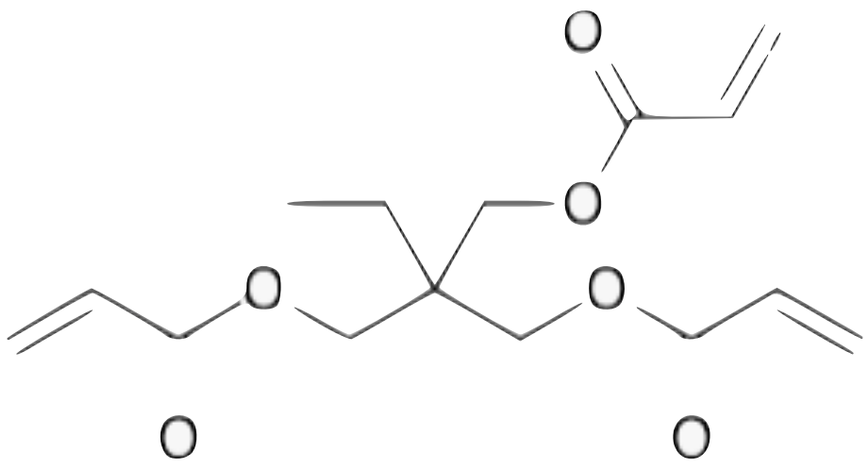


US (California) - Proposition 65 - New Listings

- **Details**
  - Trimethylolpropane triacrylate, technical grade

Low Risk unless wearable / invasive acrylic

- **Uses**
  - Intermediate
    - adhesives, sealants
    - Coatings
    - UV inks
  - *Much less common than other acrylates*

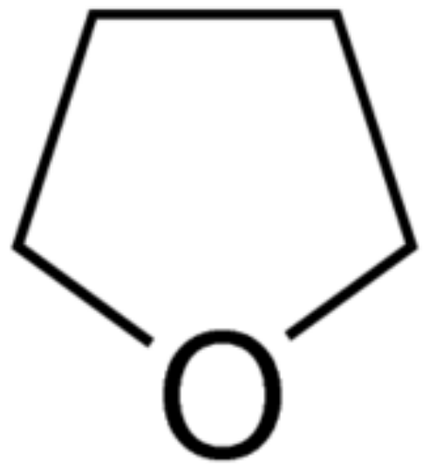


US (California) - Proposition 65 - New Listings

- **Details**
  - Tetrahydrofuran (CAS RN 109-99-9)

Low Risk unless wearable 'spandex'

- **Uses**
  - Solvent
    - coatings
    - cleaning agents
    - inks, paints
    - polymer production
    - Spandex, Lycra, Elastane
      - (polyether-polyurea copolymers)
      - trace residual solvent

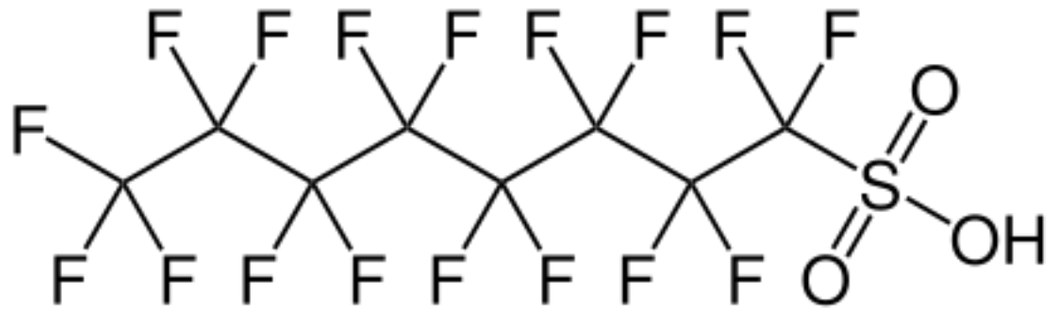


US (California) - Proposition 65 - New Listings

- **Details**
  - PFOS (CAS #1763-23-1)
    - Perfluorooctanesulfonic acid

Low Risk unless wearable / invasive fluoropolymer

- **Uses**
  - Surfactant
  - Processing aid for fluoropolymers and fluoropolymer coatings

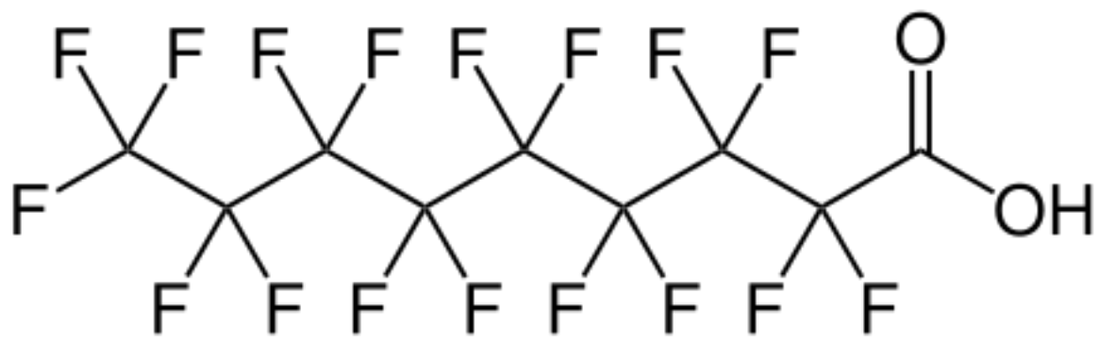


US (California) - Proposition 65 - New Listings

- **Details**
  - PFNA (CAS # 375-95-1)
    - Perfluorononanoic acid
    - LC-PFAC
    - 9 Carbon version of PFOA

Low Risk unless wearable / invasive fluoropolymer

- **Uses**
  - Surfactant
    - Processing aid for fluoropolymers and fluoropolymer coatings



Summary
Prop 65 Substances

- Significant concern for
  - Fabrics
  - Wearables
  - Medically invasive materials

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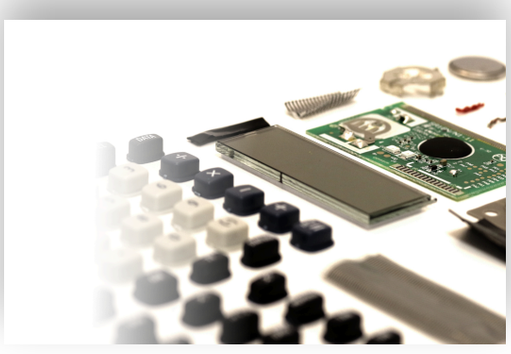
- Laboratory testing
  - For all global restricted materials regulation
    - /w version identification for regulation and list change
  - Testing 10,000s of products

- Regulatory
  - Quarterly updates (web educational)
  - Risk assessments
  - Opinions



Medical Devices
ATP Updates 2022

- Medical devices have updates to their regulated materials list for invasive / fluid / gas contacting parts at least once per year
  - Called the "Adaptation to Technical Progress" ATP

- **2022**
  - Two updates
    - ATP 15
      - Applies to medical devices registered after March 1 2022
    - ATP 17
      - Applies to medical devices registered after December 17 2022

- **ATP 15 and 17 affect primarily (but not exclusively)**
  - Fluoropolymers, acrylics, polycarbonates, epoxies, and adhesives
  - In invasive, fluid, or gas path

Medical Devices
ATP 15 - March 2022

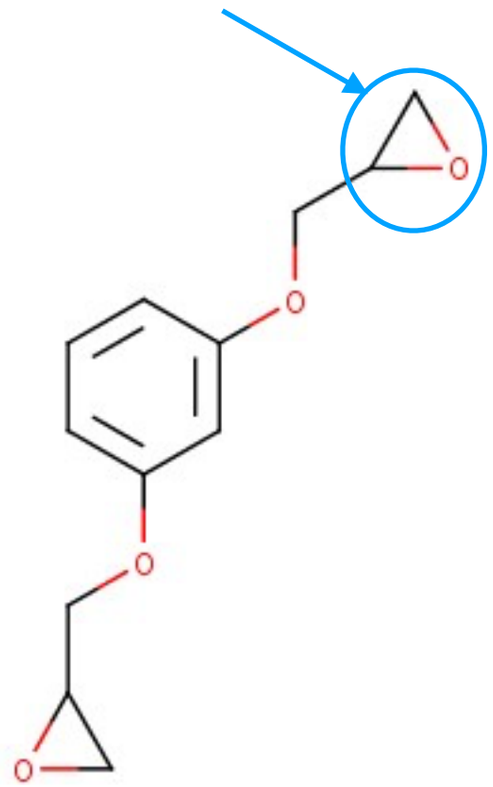
- New substances
  - silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)
  - tris(2-methoxyethoxy) vinylsilane; 6-(2-methoxyethoxy)- 6-vinyl-2,5,7,10-tetraoxa-6-silaundecane
  - dichlorodioctylstannane
  - dioctyltin dilaurate
  - stannane, dioctyl-, bis (coco acyloxy) derivs.
  - dibenzo[def,p]chrysene; dibenzo[a,l]pyrene
  - m-bis(2,3-epoxypropoxy)benzene; resorcinol diglycidyl ether
  - bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme
  - 2,2-bis(bromomethyl) propane-1,3-diol
  - 2-(4-tert-butylbenzyl) propionaldehyde
  - diisooctyl phthalate
  - 2-methoxyethyl acrylate
  - sodium N-(hydroxymethyl)glycinate; [formaldehyde released from sodium N-(hydroxymethyl)glycinate]
  - pyrithione zinc; (T-4)- bis[1-(hydroxy-.kappa.O)pyridine-2(1H)- thionato-.kappa.S]zinc
  - butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime
  - N-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]
  - bis(α,α-dimethylbenzyl) peroxide
  - Pesticides
    - ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2-(4-chlorobenzyl)-5-isopropyl-1- (1H-1,2,4-triazol-1-yl-methyl)cyclopentanol
    - flurochloridone (ISO); 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one

m-bis(2,3-epoxypropoxy)benzene

- **Details**
  - m-bis(2,3-epoxypropoxy)benzene
    - Resorcinol diglycidyl ether (EC #202-987-5)
  - Cat 1b Carcinogen
- **Uses**
  - Epoxy resins (bisphenol-A- (epichlorhydrin) epoxies)
    - Likely consumed into another chemical
    - Used in combination with
      - bpa/epichlorhydrin epoxy & 4-tert-butyl phenol
      - Potentially in photocurable resins
  - Further review ongoing
- **Other Regulations**
  - None

High Risk

'Epoxide group'
ie. EtO

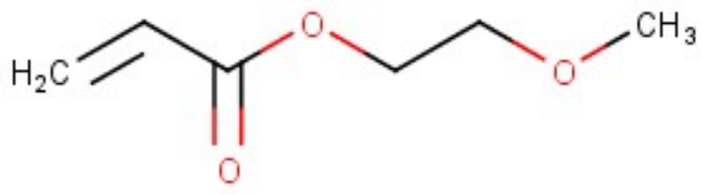


2-methoxyethyl acrylate

High Risk

- **Details**
  - 2-methoxyethyl acrylate
    - EC #221-499-3
  - Cat 1b Toxic to Reproduction
- **Uses**
  - Monomer for Poly(2-methoxyethyl acrylate) (PMEA)
    - Likely under 1,000 ppm
  - Common coating for medical devices
    - Blood compatible (antithrombogenic material)

- **Other Regulations**
  - None



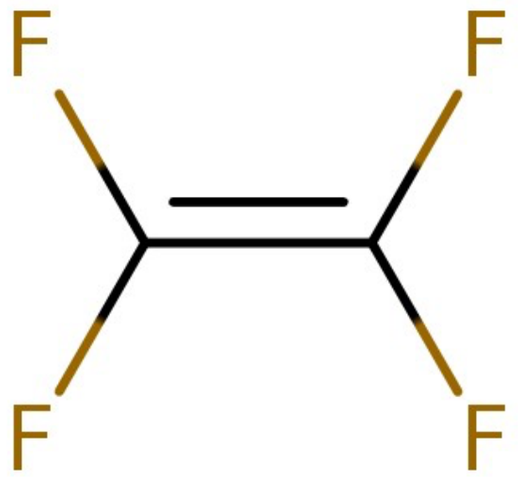
Medical Devices
ATP 17 - December 2022

- New substances
  - Boric acids and salts
    - boric acid
    - diboron trioxide
    - disodium tetraborate decahydrate
    - disodium tetraborate pentahydrate
  - Pesticides
    - mancozeb (ISO);
    - dimethomorph (ISO);
    - carbendazim (ISO);
  - tetrafluoroethylene (TFE)
  - 1,4-dioxane
  - 7-oxa-3-oxiranylbicyclo [4.1.0]heptane; 1,2-epoxy- 4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide
  - 6,6’-di-tert-butyl-2,2'-methylenedi-p-cresol; [DBMC] **(new REACH SVHC)**
  - 1,2,4-triazole
  - 3-methylpyrazole

Tetrafluoroethylene (TFE)

Low Risk

- **Details**
  - Tetrafluoroethylene (TFE)
    - PTFE monomer (EC #204-126-9)
  - Cat 1b Carcinogen
  - Highly reactive with oxygen
- **Uses**
  - Monomer for PTFE
    - Below detection limit in final PTFE
- **Other Regulations**
  - None



Tetrafluoroethylene (TFE) Highly Reactive with Oxygen

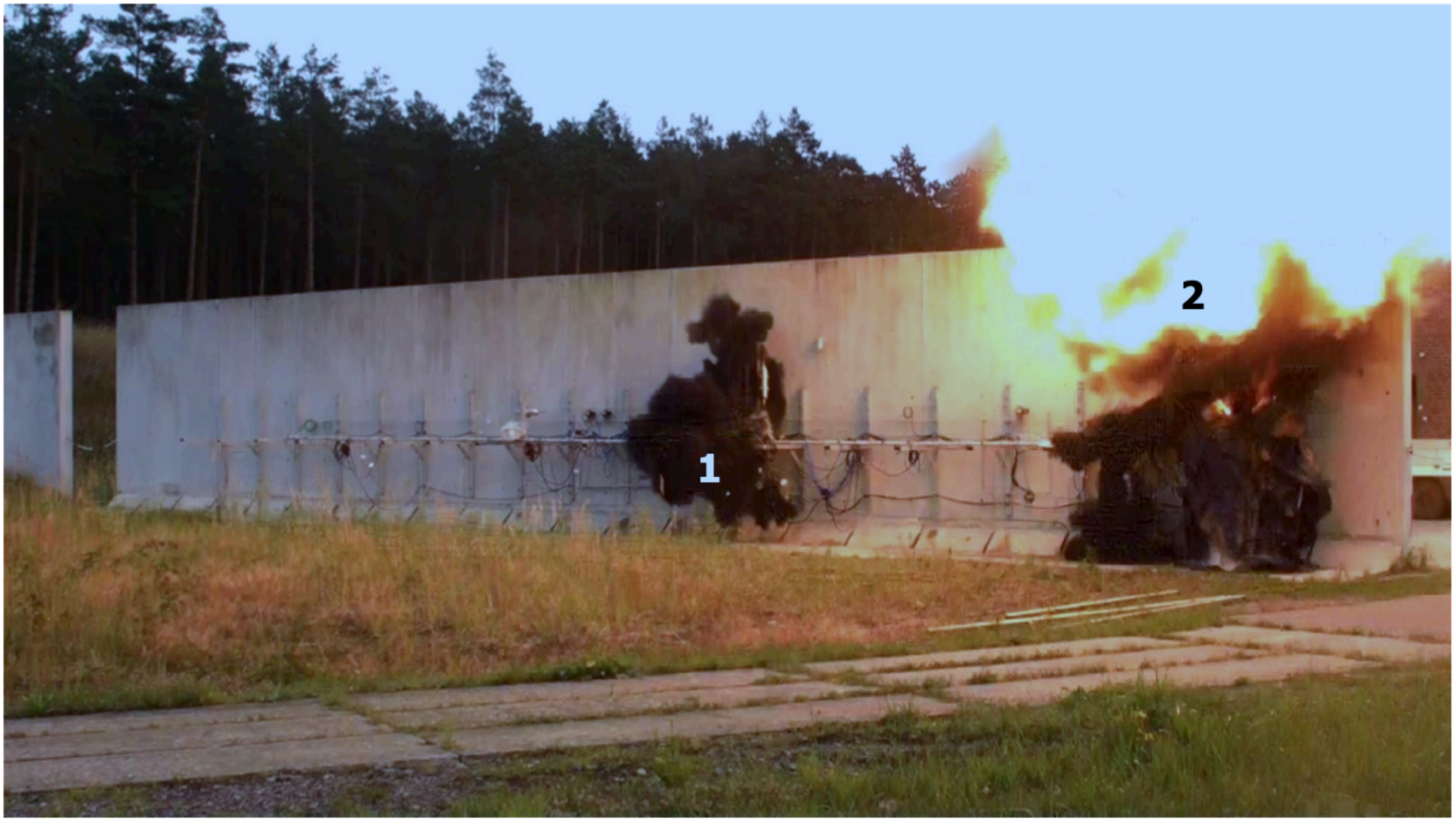


Figure 8 – Picture shot during an ignition of TFE induced by adiabatic compression of air in a large scale facility

Tetrafluoroethylene (TFE)
Highly Reactive with Oxygen

Image courtesy of Rudy Pospisil

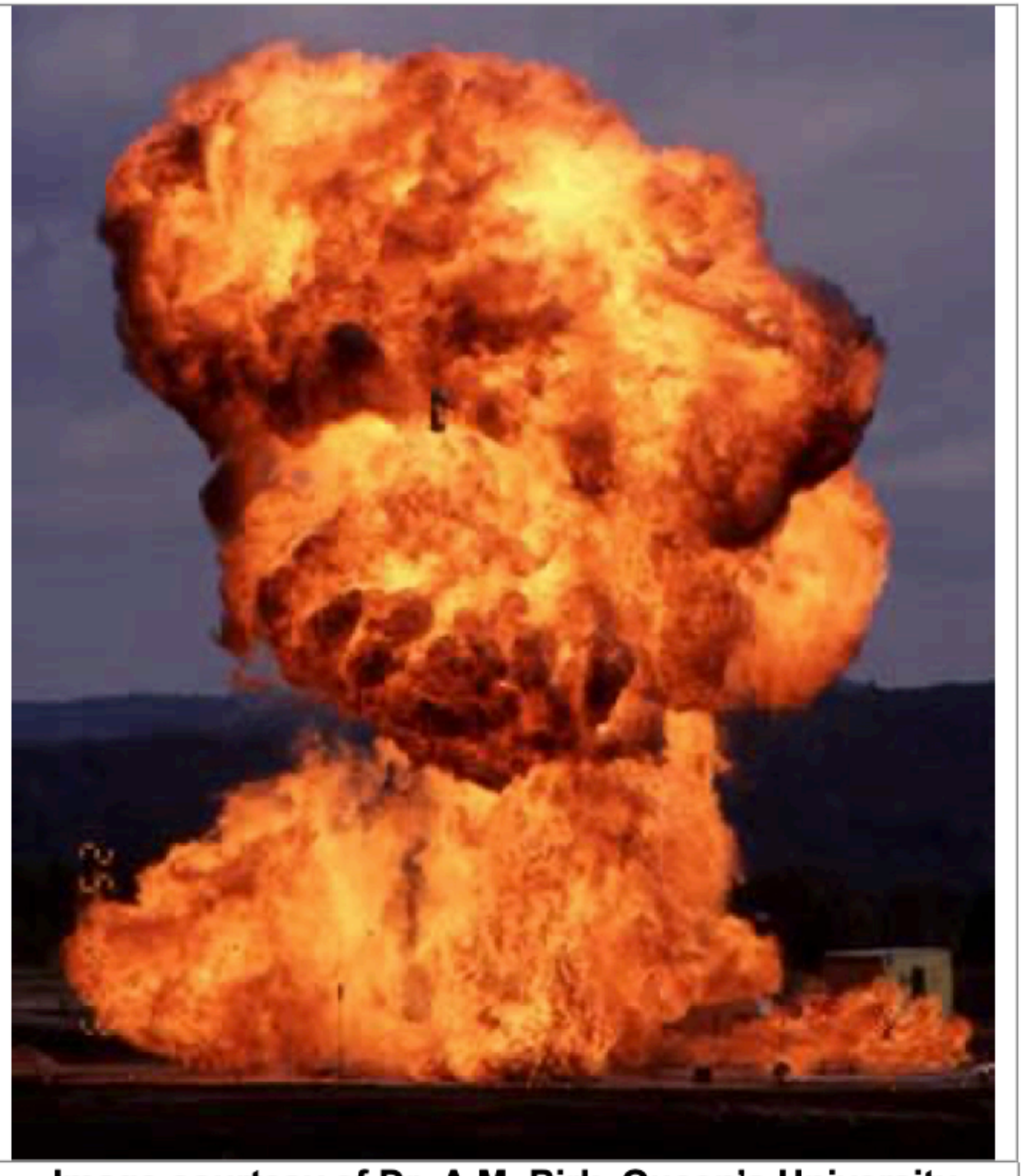


Image courtesy of Dr. A.M. Birk, Queen's University Canada

Figure 11 – Fireballs formed as a consequence of BLEVEs (Sources, left: [48], right [49])

4-vinylcyclohexene diepoxide

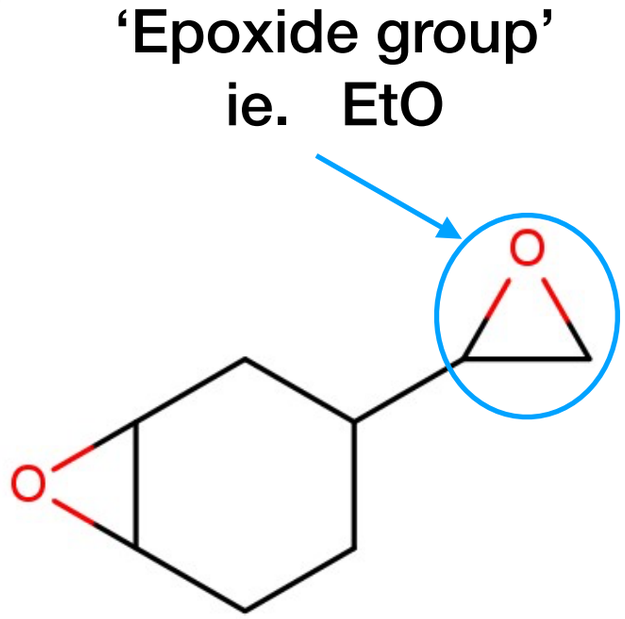
- **Details**

Low Risk

  - 7-oxa-3-oxiranylbicyclo [4.1.0]heptane
    - 1,2-epoxy- 4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide
    - EC #204-126-9
  - Cat 1b Reproductive Toxin

- **Uses**
  - Epoxide / diluent in BPA-epichlorohydrin epoxies
  - Should be fully reacted but more research required

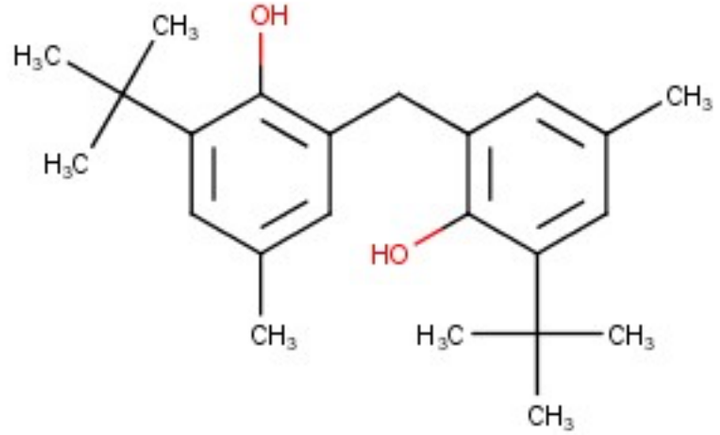
- **Other Regulations**
  - None



6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol

- **Details**
  - 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol
    - EC # 204-327-1
    - dbmc (short name)
  - Cat 1b reproductive toxin

Low Risk unless using cyanoacrylates



- **Uses**
  - Anti-oxidant
  - Very common in 'super glues'
    - Cyano acrylates (loctite)
  - Antioxidant in light coloured
    - Vulcanized rubber
- **Note**
  - If in a cyanoacrylate, it would be on the SDS of the adhesive

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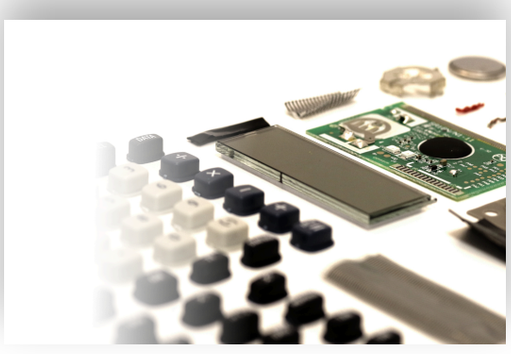


Industry Discoveries
Ethylene Oxide (EtO)

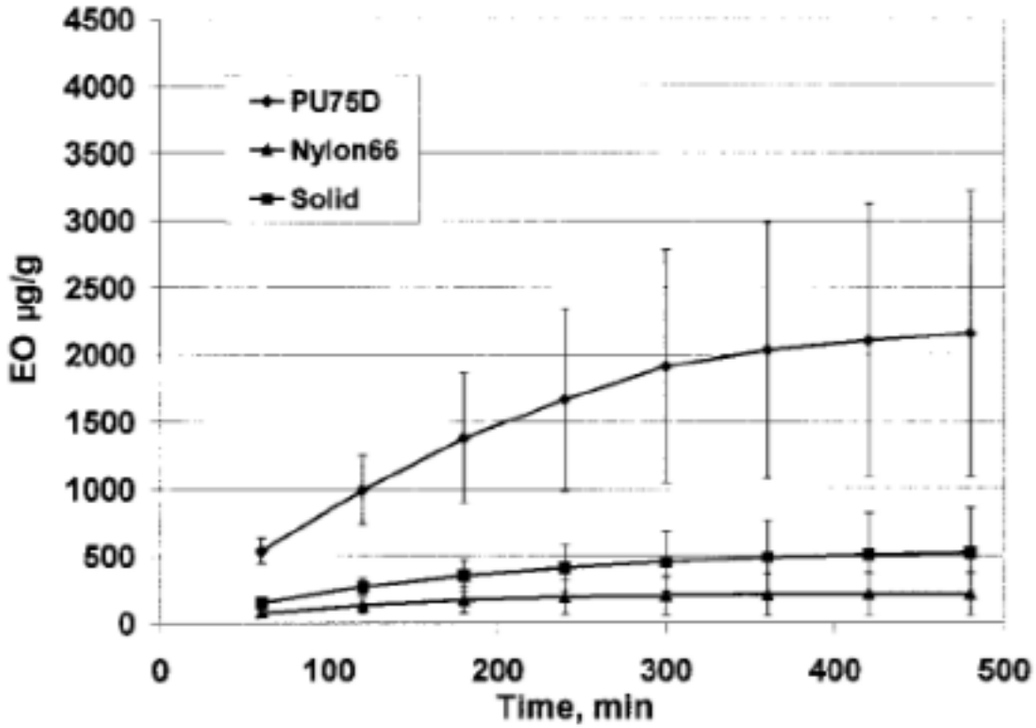
- Ethylene Oxide
  - Sterilization chemical for medical devices
  - Cat 1 Carcinogen, Mutagen, and Reproductive Toxin

- Competing pressures
  - Sterilization efficacy (lethality) vs
  - Residual EtO concentration

- Can EtO be above 1,000 ppm in an invasive material?

Literature
Residual EtO

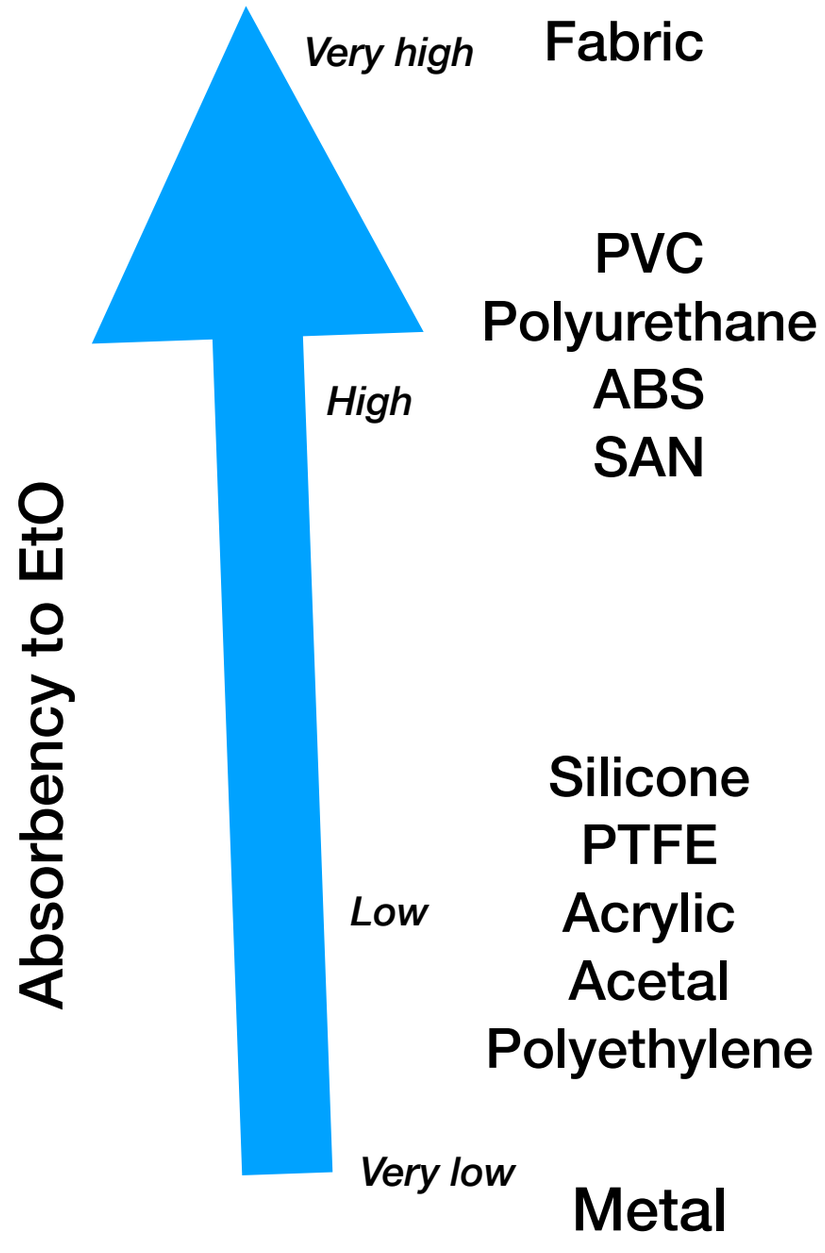
- Residual per material



Polyurethane 75D
2,000 ppm EtO
Included 12 h aeration

EtO Absorbency

- Residual EtO concentration in a material depends on its EtO 'absorbency'
  - Affected by porous nature to EtO
- High absorbency materials retain 10X to 50X more EtO than a low absorbency material



EtO Sterilizer Manufacturer Residual EtO

- Residual EtO Results

Device 1 - Rigid PVC Yankauer

	600mg/l cycle		300 mg/l cycle		
Sample	**EO (ppm)**	**EO (mg/device)**	**EO (ppm)**	**EO (mg/device)**	**% Reduction**
1	358.81	3.62	123.72	1.25	
2	360.02	3.64	126.80	1.28	
3	364.98	3.72	134.89	1.35	
Average	361.27	3.66	128.47	1.29	64%

Device 2 - Soft PVC Auxiliary Tubing

> 1,000 ppm EtO

	600mg/l cycle		300 mg/l cycle		
Sample	**EO (ppm)**	**EO (mg/device)**	**EO (ppm)**	**EO (mg/device)**	**% Reduction**
1	1555.01	30.98	632.77	12.67	
2	1379.84	26.87	636.09	12.67	
3	1893.07	37.10	798.62	16.38	
Average	1609.31	31.65	689.16	13.91	57%

Summary
Ethylene Oxide (EtO)

- Reasonable risk of being above 1,000 ppm in
  - Flexible polyurethane
  - Flexible PVC
  - Fabric

- EU MDR 10.4
  - A concern in invasive, fluid, or gas contacting material

Proposition 65
Ethylene Oxide (EtO)

- EU MDR Limit
  - 4 mg / day

- Prop 65 limit
  - 2 ug /day
  - 2,000X stricter

- In absence of specific data, an EtO sterilized device would require a Prop 65 warning.

Long Chain Perfluoroalkyl Carboxylates LC-PFAC

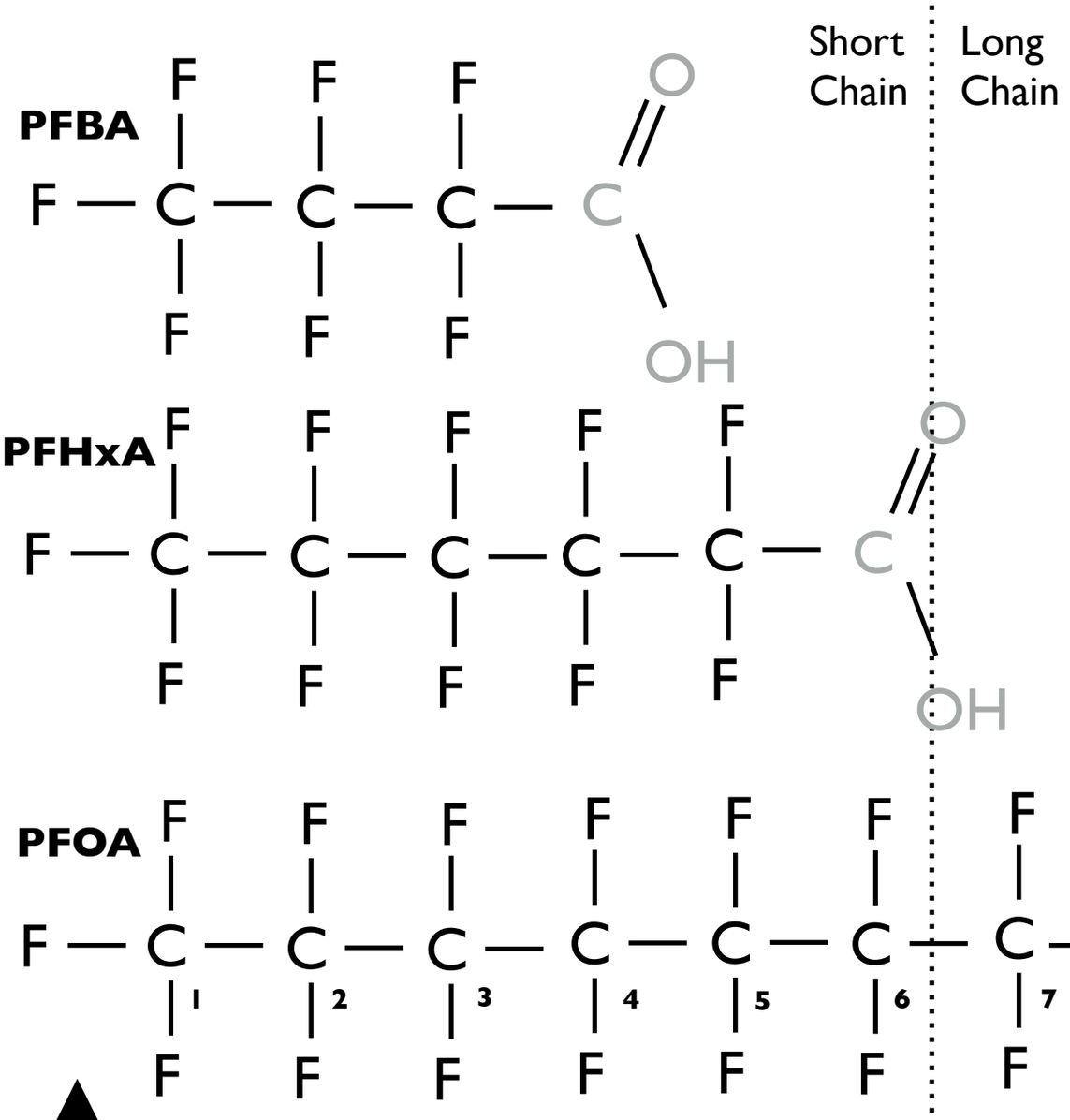
- EU POP
  - Restricts PFOA

- EU REACH
  - Restricts
    - LC-PFAC (longer versions of PFOA)
    - Chemicals that could degrade into PFOA

Perfluoroalkyl Substances (PFAS)

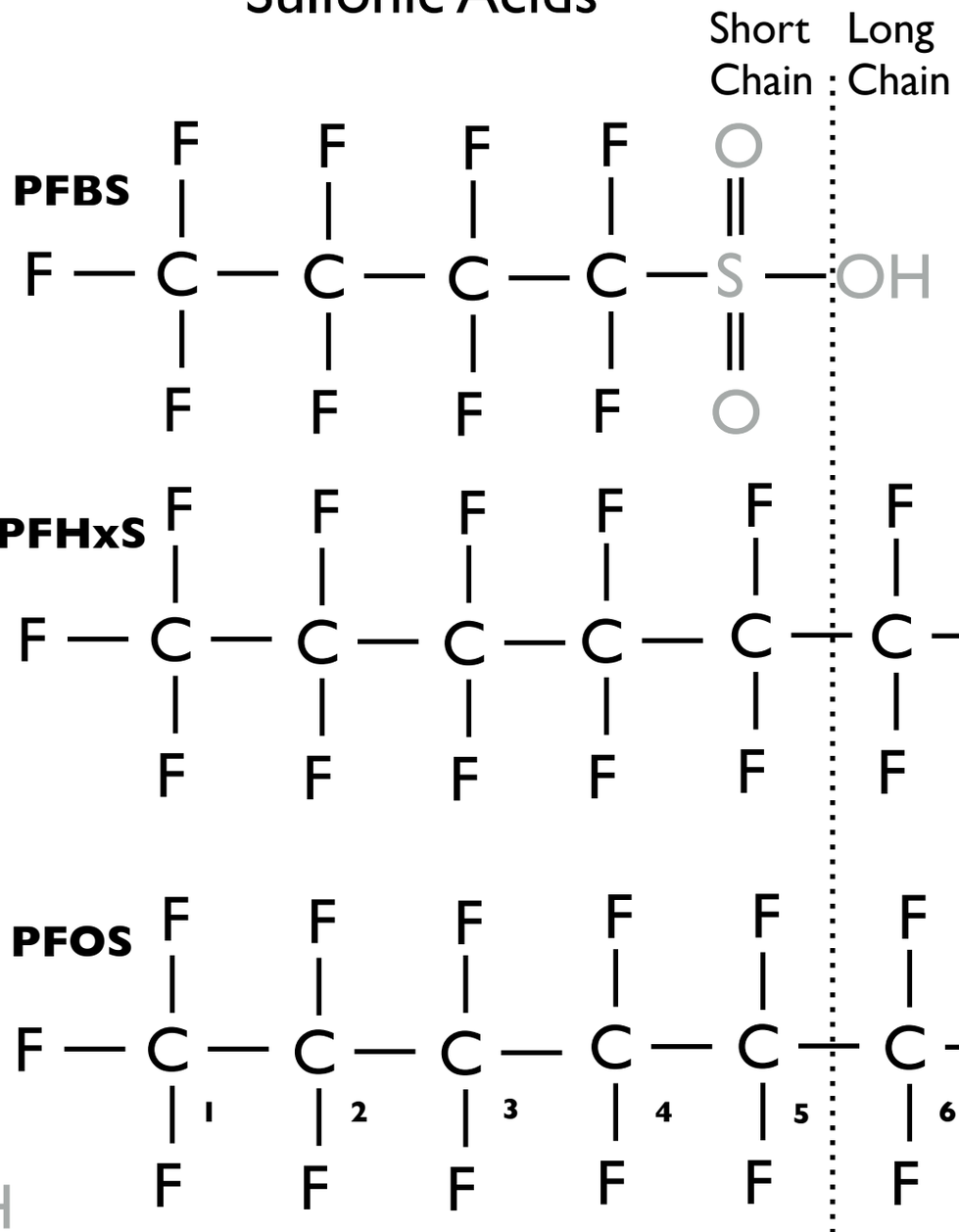
Perfluorinated carboxylate chemicals

Carboxylic Acids

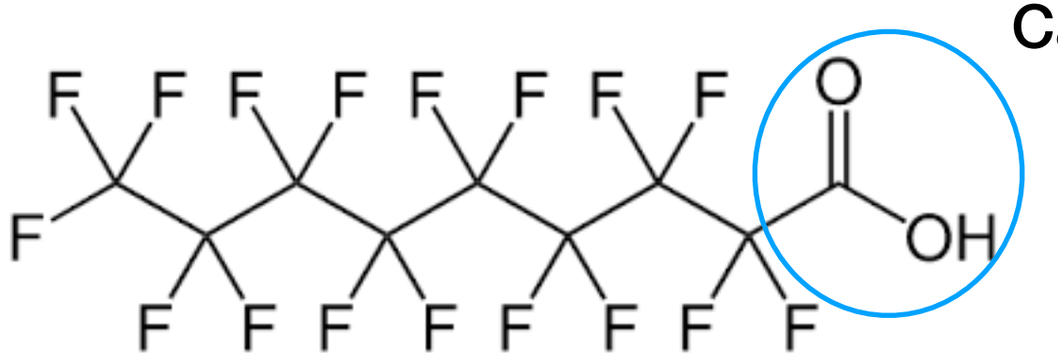


Perfluoroalkyl sulfonate chemicals

Sulfonic Acids



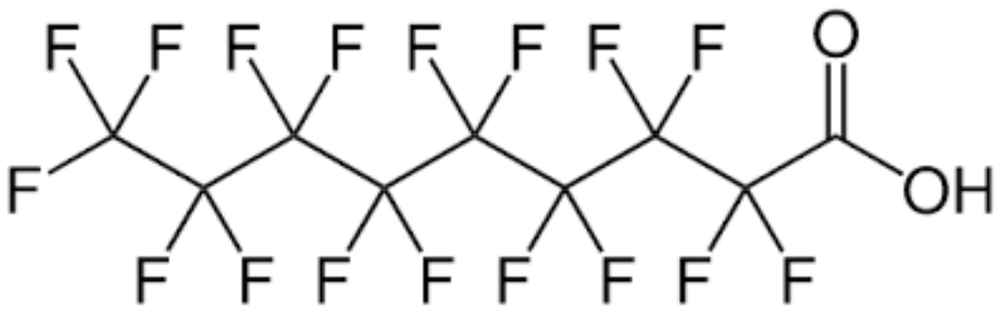
Carboxylates



Carboxylate Group

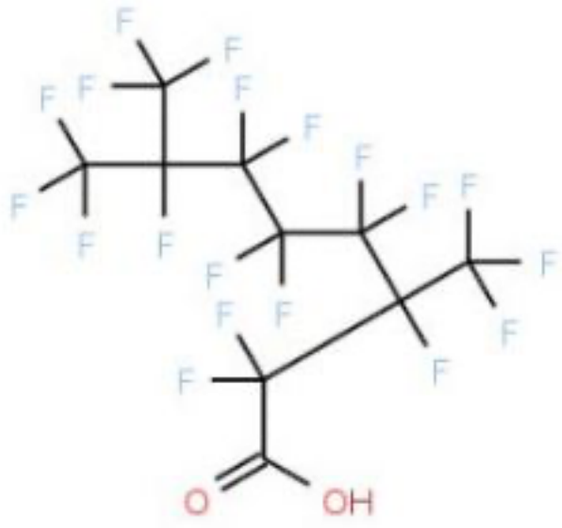
Note - ‘H’ can be Na, K, NH4, CH3 etc..

Linear



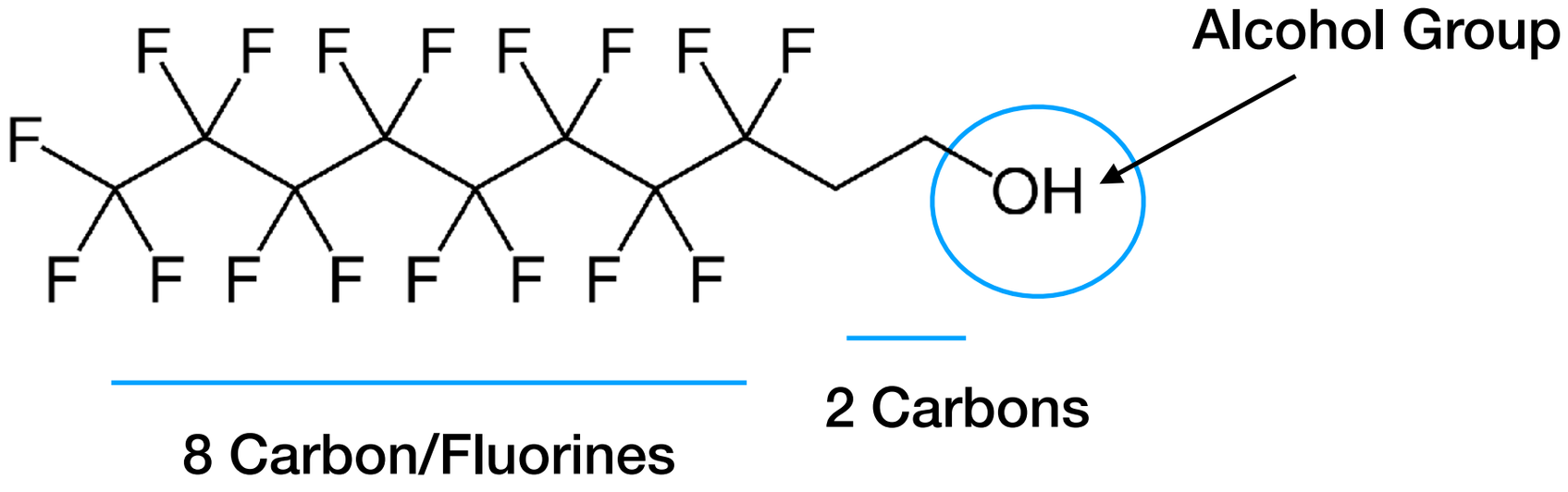
PFNA

Branched



PF-3,7 DMOA

Fluorotelomers



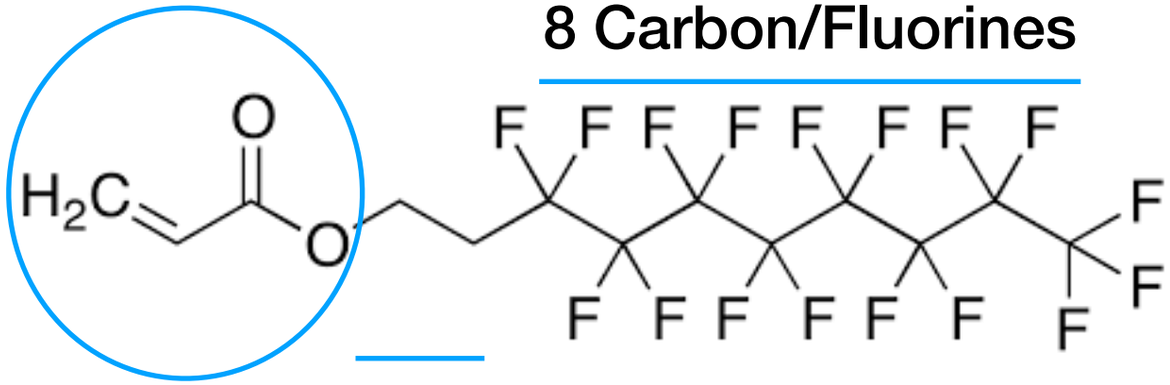
8:2 FTOH

Uses - Generally an intermediate to fluoroacrylates or similar

Included in REACH because degraded into LC-PFAC

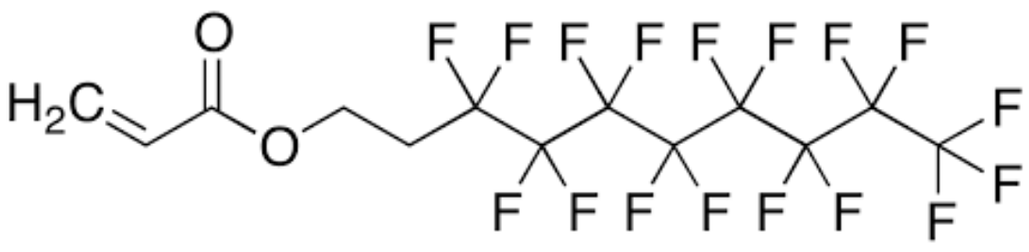
Fluoro-acrylates

Acrylate Group



8:2 FTA

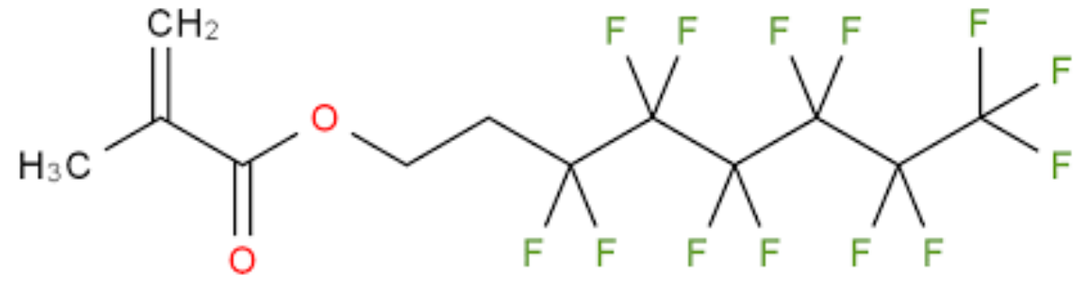
Acrylate



Acrylate

8:2 FTA

Methyl Acrylate

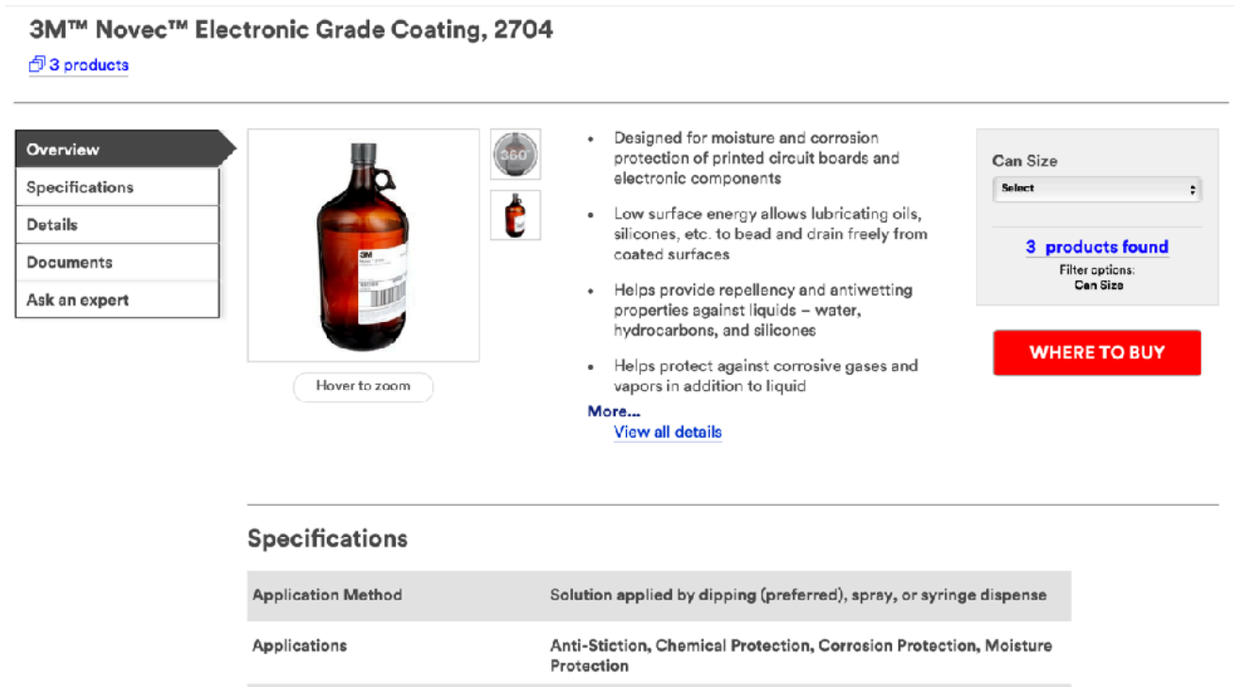


Methyl Acrylate

8:2 FTMA

Acrylates
Monomer for Fluoroacrylates

- Monomer *(in scope since degraded into LC-PFAC)*
- Uses
  - Waterproof coatings
  - Graffiti resistent concrete
  - Water resistant circuit boards (conformal coating)
  - Ultra thin coating



3M™ Novec™ Electronic Grade Coating, 2704

3 products

Overview
Specifications
Details
Documents
Ask an expert

Hover to zoom

- Designed for moisture and corrosion protection of printed circuit boards and electronic components
- Low surface energy allows lubricating oils, silicones, etc. to bead and drain freely from coated surfaces
- Helps provide repellency and antiwetting properties against liquids – water, hydrocarbons, and silicones
- Helps protect against corrosive gases and vapors in addition to liquid

More...
View all details

Can Size
Select

3 products found
Filter options:
Can Size

WHERE TO BUY

Specifications

Application Method	Solution applied by dipping (preferred), spray, or syringe dispense
Applications	Anti-Stiction, Chemical Protection, Corrosion Protection, Moisture Protection

LC-PFAC - High Risk Materials

- LC-PFAC (25 ppb) common locations
- Fluoro Coatings
  - fabric
  - membranes
  - steel mesh screens
  - silicone touch pads
  - Non-stick food contact surfaces
  - High durability touchscreen
- Solid fluoropolymers
  - PTFE (Teflon), FKM (Viton), PVDF, FEP, etc.
  - Lithium battery cathodes
- Fire fighting foams

REACH / POP Limits (+ EU MDR)

- LC-PFAC
  - 25 ppb

- Fluorotelomers and Acrylates
  - 260 ppb

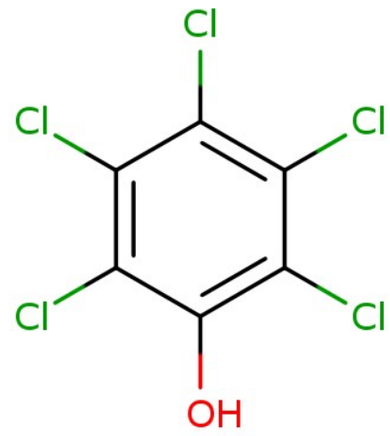
- *Plus -*
- PFOA, PFNA, PFDA, APFO, PFOS (EU MDR)
  - 1,000 ppm (not very relevant)

New POP Substance

- **Details**
  - Pentachlorophenol (EC# 201-778-6)

Low Risk unless outdoor industrial wood or fabric

- **Uses**
  - Pesticide / biocide / preservative
    - Outdoor wood
    - Outdoor industrial fabric
      - Ie. tarps etc..



- **Change**
  - Applies to articles (physical products) with a restriction of 5ppm

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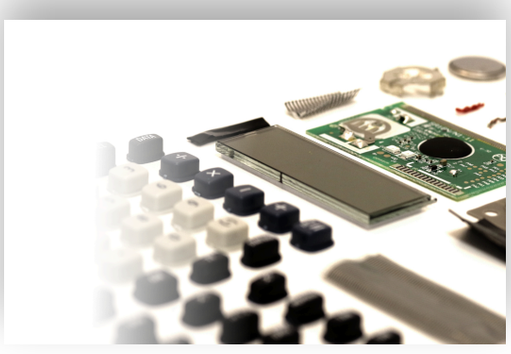
- Laboratory testing
  - For all global restricted materials regulation
    - /w version identification for regulation and list change
  - Testing 10,000s of products

- Regulatory
  - Quarterly updates (web educational)
  - Risk assessments
  - Opinions



Risk Assessments

- REACH SVHC, REACH Restrictions, Prop 65, POP, EU MDR, and more…..

Claigan

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Kanata, ON, Canada, K2K 2B5

California Proposition 65 - December 2021 Updates

Risk assessment of potential presence in physical products (articles) for Prop 65 substances listed in December 2021[1] [2] [3].

Substance	Risk Level	Use/Justification	Materials of Risk
Tetrahydrofuran (thf)	Low risk except for wearables	Aprotic polar solvent. Solvent for spandex / elastane manufacture. Solvent for PVC (laboratory use). Very high NOAEL - risk limited to wearables or similar	Wearable elastomeric polyurethane fibers (spandex / elastane / lycra)
2-ethylhexyl Acrylate	Low risk except for wearables and implantables	Acrylate intermediate / monomer to manufacture acrylics. Residual amount in the final article. The high NOAEL limits the risk to wearables or similar	Wearables acrylic based materials including acrylic paints. Dental implants
Methyl Acrylate	Low risk	Acrylate intermediate /	Wearables acrylic

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