# SANITARY DESIGN: ELASTOMER COMPATIBILITY

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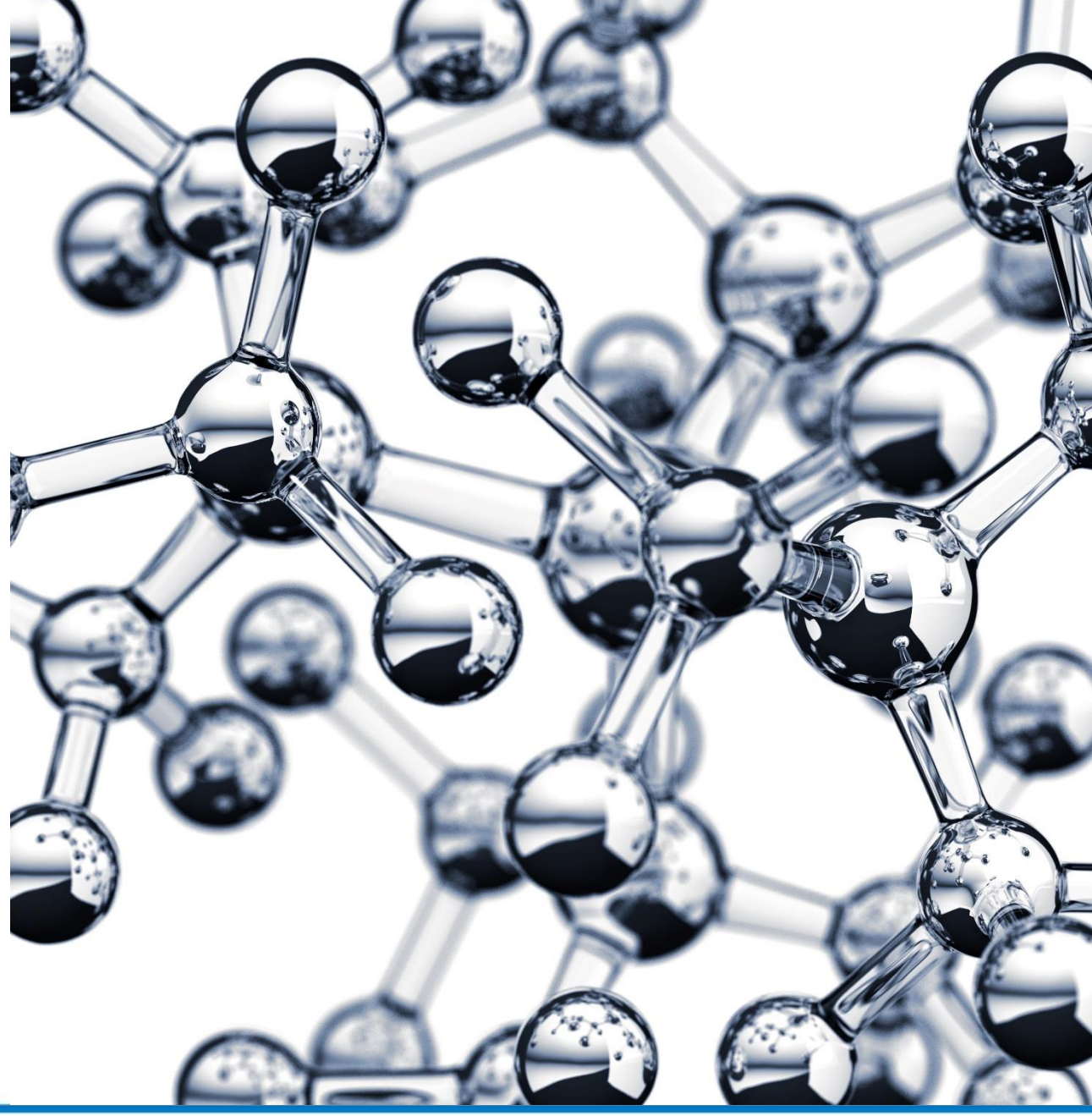
Area Technical Support



# AGENDA

- What is an elastomer
- Regulations and Standards
- Making the right choice
- Why is compatibility important to Sanitary Design
- How to determine compatibility
- Examples of Incompatible

# WHAT IS AN ELASTOMER

Definition

A substance made from polymers joined with a slightly cross-linked structure.  Characteristics include high elongation, flexibility and elasticity. Stretchy material that can return to its pre-stretched shape.

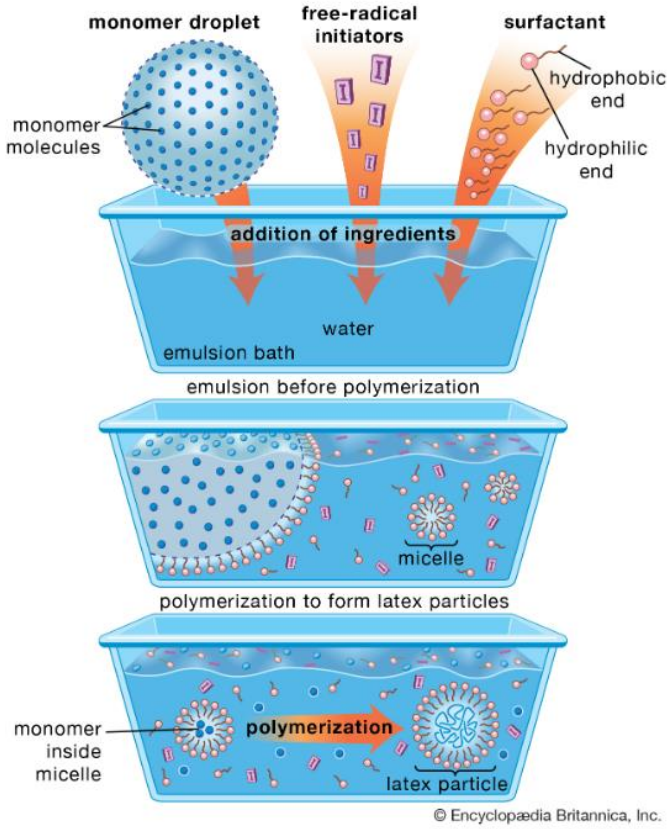
Shortened: Elastic Polymer

Subset of Polymers

AKA: Rubber like material

Unique Identifier: CAS Number

# SUPPLY CHAIN




Gum Rubber

Rubber Compounder

Part Manufacturer

Equipment Manufacturer

Distributor

Img Src: Encyclopedia Britannica, Preferred Compounding Whitewater, MI, HB Fuller, Precision Polymer

# WHAT IS AN ELASTOMER

List of Common Elastomers

| Common Name | Trade Name | Temperature Range | Usual Color | Usual Hardness Range |
|---|---|---|---|---|
| **Nitrile** Butadiene / Buna'N' (NBR) | Chemigum, NySyn, Hycar, Paracril, Krynac | -65 F to 250 F | Black | 50-90 Shore A |
| **Silicone** (SI) | Silastic, Thermoflex | -80 F to 450 F | Red, Blue, Yellow | 50-90 Shore A |
| Fluorocarbon (FKM, FMC) | **Viton**, Fluorel, Technoflon | -31 F to 437 F | Black, Brown, Green | 60-95 Shore A |
| Hydrogenated Acrylonitrile Butadiene (**HNBR**, HSN) | Therban, Zetpol, Tornac | -40 F to 300 F | Green, Black | 60-80 Shore A |
| Chloroprene (CR) | **Neoprene** | -65 F to 275 F | Black | 50-90 Shore A |
| Ethylene Propylene (**EPDM**) | Vistalon, Epsyn, Fpcar, Royalene, Nordel | -80 F to 300 F | Red, Blue, Yellow | 50-90 Shore A |
| Styrene Butadiene/Buna"S" (SBR) | GRS | -40 F to 212 F | Black | 70-90 Shore A |
| **Fluorosilicone** (FSI, FVMQ) | Silastic LS, FSE | -85 F to 350 F | Light blue | 50-90 Shore A |
| Perfluoroelastomers (FFKM) | **Kalrez** | -31 F to 600 F | Black | 75 Shore A |

# WHAT IS AN ELASTOMER

Formulation and Process

- Mix of base materials and processing to create a desired elastomer with unique characteristics

- Example: Natural Rubber
  - Sap from rubber tree is combined with water and another compound like Morning Glory extract to harden the rubber
  - Press the mixture after it sets up
  - Hang to dry

- Synthetic elastomers have more complex processes designed to link prepared monomers together that are usually made from petrochemicals

# REGULATIONS

- Food Contact Substances
  - FDA - may be regulated by 21 CFR Parts 170-199, if not FCN, FAP, ToR, No migration
    - cGMPs 117.40 Equipment and Utensils
    - 21 CFR § 177.2600 Rubber articles for repeated use
      - Extraction tested to CFR 21 § 177.2600(e,f)
    - FDA/USDA grade materials
    - 21 CFR § 178.3570, Incidental Contact 177.1500 Perfluorocarbon Resins.
    - 21 CFR § 180.22 Acrylonitrile copolymers (safely used on an interim basis of articles intended for use in contact with food)
    - FDA Compliant material suitable for dry food contact applications
  - USP Class VI – EPDM, Viton, Silicone and PTFE
- EC1935/2004 food contact and EC2023/2006 GMPs compliant

# STANDARDS

- Sanitary Design
  - 3-A Standard 18-03 Seals: Class I (300°F Ex. Silicone), Class II (250°F Ex. NBR and EPDM), Class III (120°F Ex. HNBR), Class IV (100°F ) *Cleaning/bactericidal temperature 180°F for all classes
- Characteristics
  - ASTM Test Methods
- Storage:
  - ISO 2230: Rubber Products
  - SAE-AS5316
- Food Grade and Antimicrobial
  - ASTM JIS Z2801
- USP (United States Pharmacopedia) ‘not government
  - USP Class VI establishes a standard for medical grade elastomer sealing solutions – focus on medicine and healthcare but may consider if multipurpose design
- NSF/ANSI
  - NSF/ANSI-51, Food Equipment Materials (restaurant and commercial kitchen)

# CHOOSING AN ELASTOMER

Making the Right Choice

| Properties | Compatibility | Storage |
| --- | --- | --- |
| • Durability<br>• Flexibility<br>• Temperature<br>• Components | • Food or Beverage<br>• Cleaning or Sanitizing | • Length of Time<br>• Conditions |

# CHOOSING AN ELASTOMER

Shelf-Life, Combination Properties

Shelf-life – Several Unlimited, some 15 years, Polyurethane (5-10 years), Styrene Butadiene (Buna-S or SBR) (3 years)

- Store them properly – no stress, moderate to low humidity, avoid sunlight, 60-100 F, mixing elastomers, not in contact with liquids, avoid some metals (copper, iron, manganese)

Can be combined like PTFE Encapsulated Viton o-rings for example?  Combine exterior chemical resistance with internal compression set resistance.

Metal Detectable is usually an elastomer that has been mixed with a metallic powder to make the object metal detectable.

# WHY IS COMPATIBILITY IMPORTANT

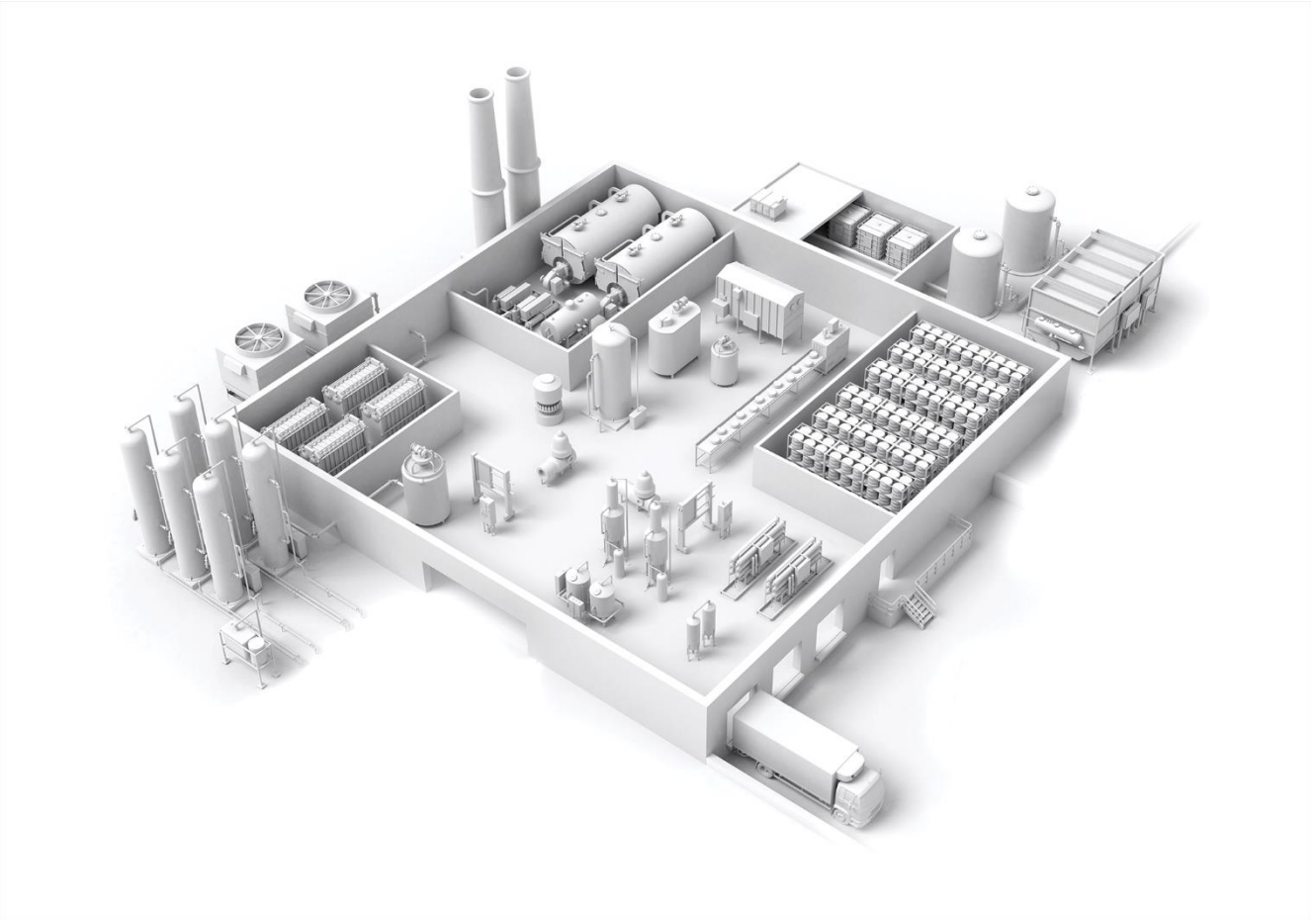
## Sanitary Design

- The design of equipment and facilities will require flexible materials for a variety of reasons
- Those materials have to be easy to clean to a microbiological level
- The required properties of elastomers makes them **particularly susceptible** to changes that can cause poor sanitary conditions
- Selecting the right elastomers and maintaining or replacing them is the best way to ensure proper operating performance as well as maintaining acceptable sanitary conditions
- Elastomers have such great variety that can easily be misunderstood and misused

# WHY IS COMPATIBILITY IMPORTANT

Impacts

- Food Safety
  - Toxicological
  - Microbiological
  - Physical
- Quality
  - Product quality changes
    - Visual
    - Taste
- Performance
  - Equipment failure
  - Product loss



# HOW TO DETERMINE COMPATIBILITY

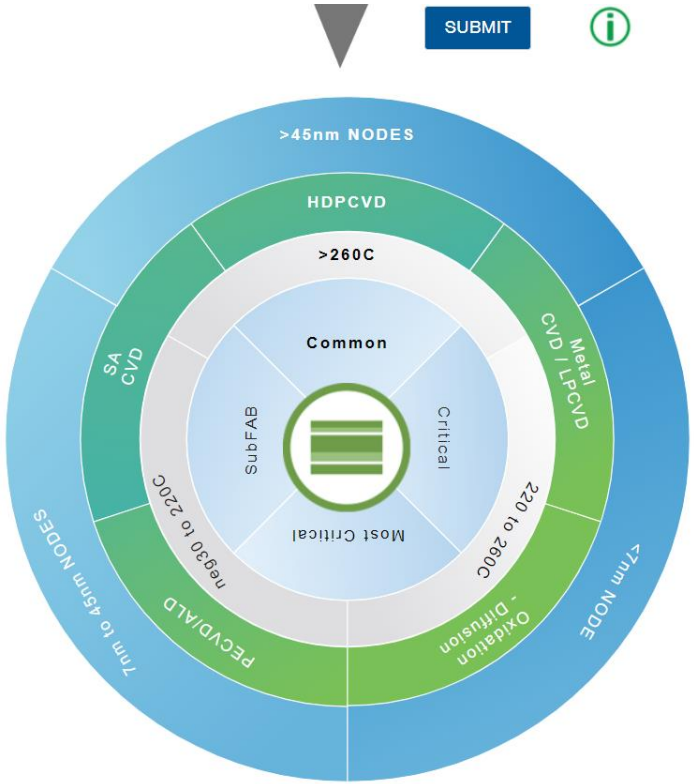
Selection and Fit for Purpose (Specifications)

- Part of Selecting the Correct Elastomer for the Operating Environment
  - Success or Failure is hugely dependent on selecting the right elastomer
    - Properties (ASTM or ISO)
      - Durometer (Hardness, Compressibility)
      - Flexibility
      - Temperature range
      - Shelf-life
      - FDA approved
    - Resistance
      - Ozone
      - UV
      - Weather
      - Chemical
      - Oil
      - Cold
    - Design
      - Metal detectable
      - Labyrinth seal or other way to prevent high-pressure sanitation leakage

# HOW TO DETERMINE COMPATIBILITY

## Look it Up – Selection Guides

- Many parts manufacturers or distributors will have guides of varying use

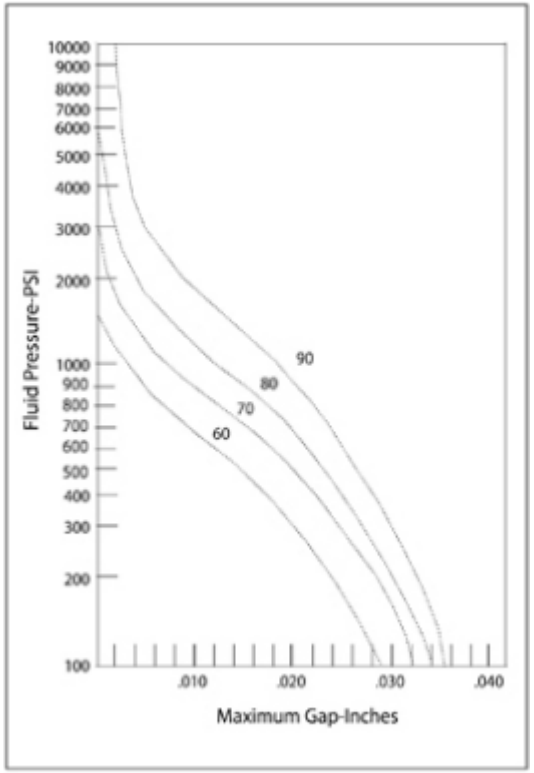



**Buna-N (Nitrile)**

| Symbol | High Temp | Characteristics | Common Identifier |
|---|---|---|---|
| U | 225 F | ✓✓ Very good with oil-based products<br>✓ Good with acid and caustic (2% caustic max; 0.5% acid max)<br>✗ Loses life at high temperatures | Black with red dot |

**Viton® (Steam Resistant Flouroelastomer)**

| Symbol | High Temp | Characteristics | Common Identifier |
|---|---|---|---|
| SFY | 400 F | ✓✓ Very good with acid and most oils<br>✓ Good with caustic and steam<br>– Higher cost<br>✗ Poor flexibility at low temperatures | Black with yellow and white dot |



# HOW TO DETERMINE COMPATIBILITY

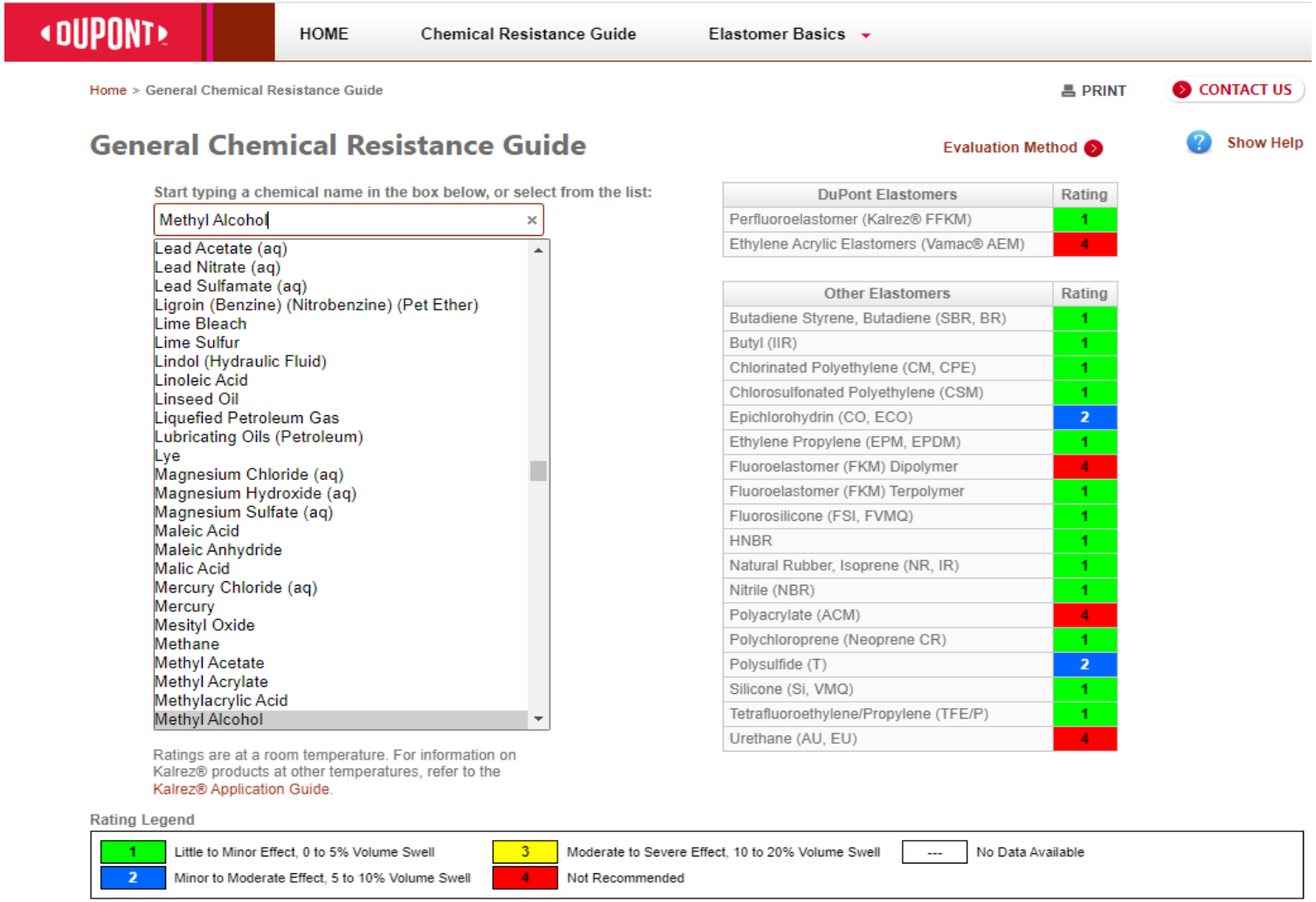
## Chemical Compatibility Guide - Focus

- Many companies that make materials, equipment or sometimes chemicals will produce Compatibility or Chemical Resistance Guides
  - Material or Equipment – may have 100s or 1000s of chemicals included for comparison
  - Chemical Companies – may have dozens or 100s of materials included for comparison
  - Some with temperature, most without
- Example Fine Print
  - This information is to the best of our knowledge accurate and reliable. However, Precision Polymer Engineering Ltd makes no warranty, expressed or implied, that parts manufactured from this material will perform satisfactorily in the customer's application. It is the customer's responsibility to evaluate parts prior to use, especially in applications where their failure may result in injury and/or damage. It should also be noted that all elastomeric parts have a finite life. Therefore a regular program of inspection and replacement is strongly recommended. In non-black grades of elastomer, it is possible to observe slight variations in color. This is normal and is inherent in the part; it is not indicative of foreign matter. These color variations are not expected to adversely effect the performance of the part. The material properties above should not to be used for specification purposes.

# HOW TO DETERMINE COMPATIBILITY

Look it Up - Guides

- Guide Features to Look For
  - Multiple types of Elastomers
  - Evaluation Method
  - Chemical Match




https://mscrm-dupont.secure.force.com/CRG_Home?force=1

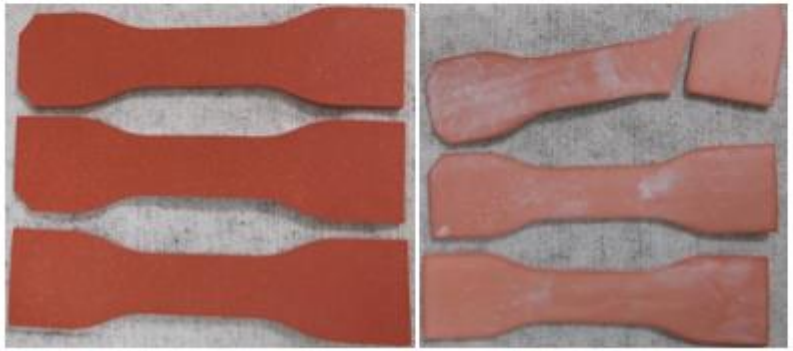
# HOW TO DETERMINE COMPATIBILITY

Test It Yourself - Visual Inspection

- When to test
  - Incomplete information or poor match with your conditions
    - References and published information may likely only get you part of the way
  - Critical that failure does not occur
  - You may need to set up a trial or test to gain confidence
- What to Look For
  - Signs of permanent distortions (like flats or creases)
  - Mechanical damage (cuts, abraded areas, tears)
  - Change of surface condition (hardening, softening, tackiness, or surface cracking)

# HOW TO DETERMINE COMPATIBILITY

## Chemical Compatibility Testing Silicone Rubber



28 day soak test
Concentrate
50 deg C

| Chemistry | % Mass Change | % Volume Change | % Tensile Strength Change | % Hardness Change |
|---|---|---|---|---|
| Product A | 3.5474 | 6.0186 | -43.76 | -15.89 |
| Product A with Additive | 3.4329 | 5.7713 | -41.40 | -15.63 |
| Product B | 4.9994 | 8.6674 | -46.85 | -23.70 |
| Product B + | 5.1024 | 8.8316 | -44.42 | -24.74 |
| Standard | 10.7488 | 18.7156 | -47.51 | -24.74 |
| DI Water | 0.3564 | 0.6260 | -0.66 | 0.00 |

# HOW TO DETERMINE COMPATIBILITY

Chemical Compatibility Testing Methods Discussion

- What to Look For
  - Signs of permanent distortions (like flats or creases)
  - Mechanical damage (cuts, abraded areas, tears)
  - Change of surface condition (hardening, softening, tackiness, or surface cracking)
  - Change in dimensions (swelling, shrinking, elongation, volume, mass)
  - Change in other properties (durometer, flexibility, tensile strength)

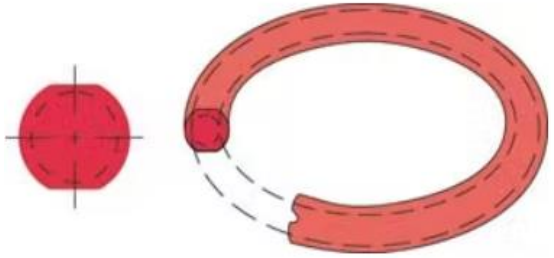
# HOW TO DETERMINE COMPATIBILITY

What role can you play to seek out new compatibility information

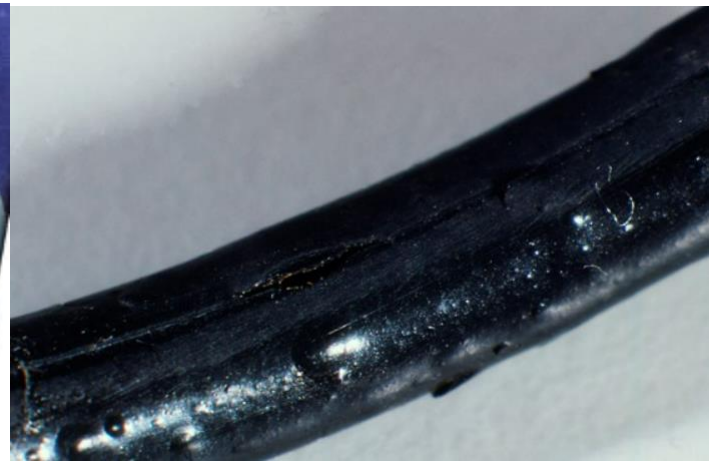
- Equipment Manufacture or Facility Construction
  - Understand process including sanitation to identify new conditions
  - Provide specifications to compounders
- Chemical Providers
  - Testing database
  - New testing in specific conditions
- CPG / Food and Beverage Manufacturers
  - Ongoing performance evaluation
  - Sanitary design reviews
  - Use selection guides

# INCOMPATIBLE EXAMPLES

Common Failure Modes



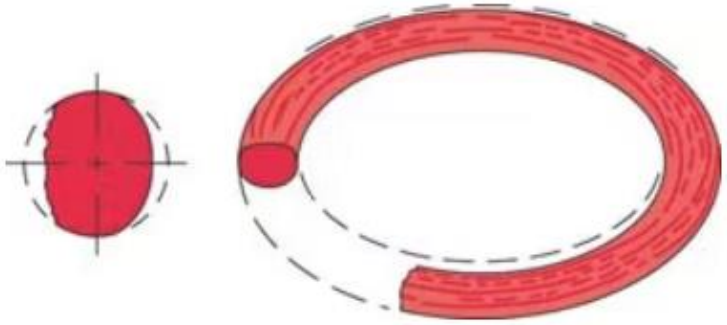
Swell



Chemical Attack

Compression Set

Installation Damage



Wear


ECOLAB®