Selection of Materials for Products Subject to Sterilization Processes

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STERIS

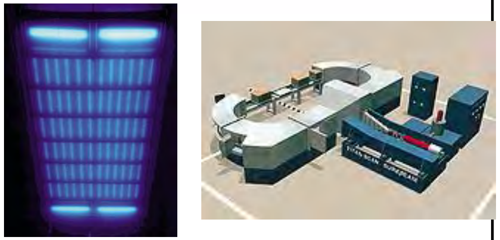
Applied Sterilization Technologies

Compatibility of Materials Subject to Sterilization Topics Covered

- **1. Materials selection (Modality Specific Effects)**
  - Info to help choose sterilization modality compatible materials.

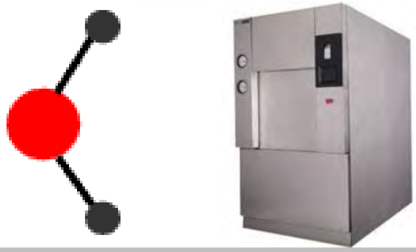
- **2. Processing & design**
  - Guidance on recognizing the effect that processing and design in manufacture can have on the long term performance of a product and importance of optimizing functional performance (even after sterilization).

Common Modalities



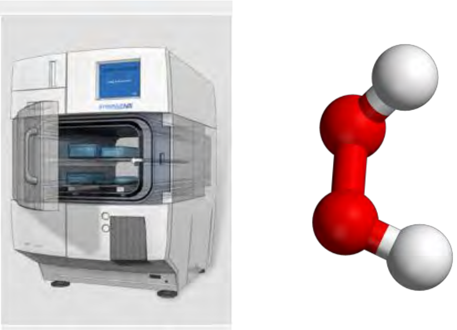
Radiation

EO



Moist Heat (Steam)

Dry Heat



Hydrogen Peroxide

Ozone

Radiation, EO, Etc. In Standards each have features to Consider

Radiation	EO	Moist Heat (Steam)
• Dose / Dose range • Environment (O_2, H_2O) • Dose Rate – Temperature – Oxygen chemistry	• EO (and diluent) • Temperature • Humidity • Vacuum (levels and/or change rate)	• Temperature • Water or water vapor • Pressure and/or vacuum (levels and/or change rates)
Dry Heat	**Hydrogen Peroxide**	**Ozone**
• Temperature (high) • Pressure and/or vacuum (levels and/or change rates)	• H_2O_2 – vapor (and gas plasma) • Humidity • Temperature • Vacuum	• O_3 • Temperature • Humidity • Vacuum (level and/or change rate)

Materials Selection Criteria

- Selecting the right Material(s) can be one of the most complex decisions for a new or revised product.
- Doing it properly also gives you one of the best returns on investment you will make in product development.
  - Prevents delays in product development
  - Provides a product that tolerates flexible sterilization cycles
  - Can effect throughput or scheduling in a sterilization cycle
  - Can effect product shelf life and potential applications

Key Criteria for Material

- Functional
- Physical constraints (i.e. size, profile, strength)
- Environmental (biological fluids, cleaners, solvents)
- Chemical interactions needed (bonding properties, fluid contact)
- Electrical (dielectric strength, conductivity, UL rating)
- Optical (transparency, translucency, opacity, color desired)
- Misuse (i.e. reuse or other applications)
- Cost (price per pound or effects on manufacturing process costs)
- Must be able to tolerate sterilization process selected and not only be sterile but still work.

Materials Selection Criteria Resources

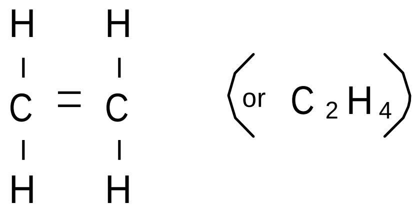
- More and better polymer choices are available each year.
  - New formulations especially
- Select primary & alternate materials to qualify early in development (avoid restriction to a single material). Many variations available on base polymers so easy to do.
- Don’t need encyclopedic knowledge of materials (helps if you have this). Use all available resources in decision process.
  - a computer aided search (Remember this is research not just search; Google is not final answer)
  - Resin suppliers
  - In house experiences or materials experts
  - Publications, standards (AAMI TIR 17)
  - Trial and error (literature is not the final answer, must try it)

The Chemistry of Plastics "Polymer Chemistry" – Polymerization

Polymer Chemistry

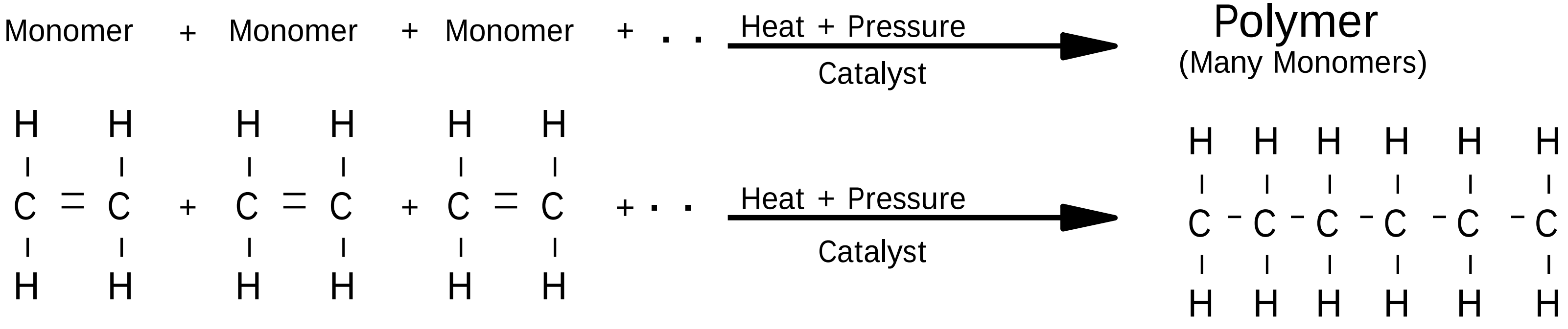
Monomer – Greek Word Meaning "one part"

Ethylene



$$\begin{array}{ccc} H & & H \\ | & & | \\ C & = & C \\ | & & | \\ H & & H \end{array} \quad \left(\text{or } C_2H_4\right)$$

POLYMERIZATION



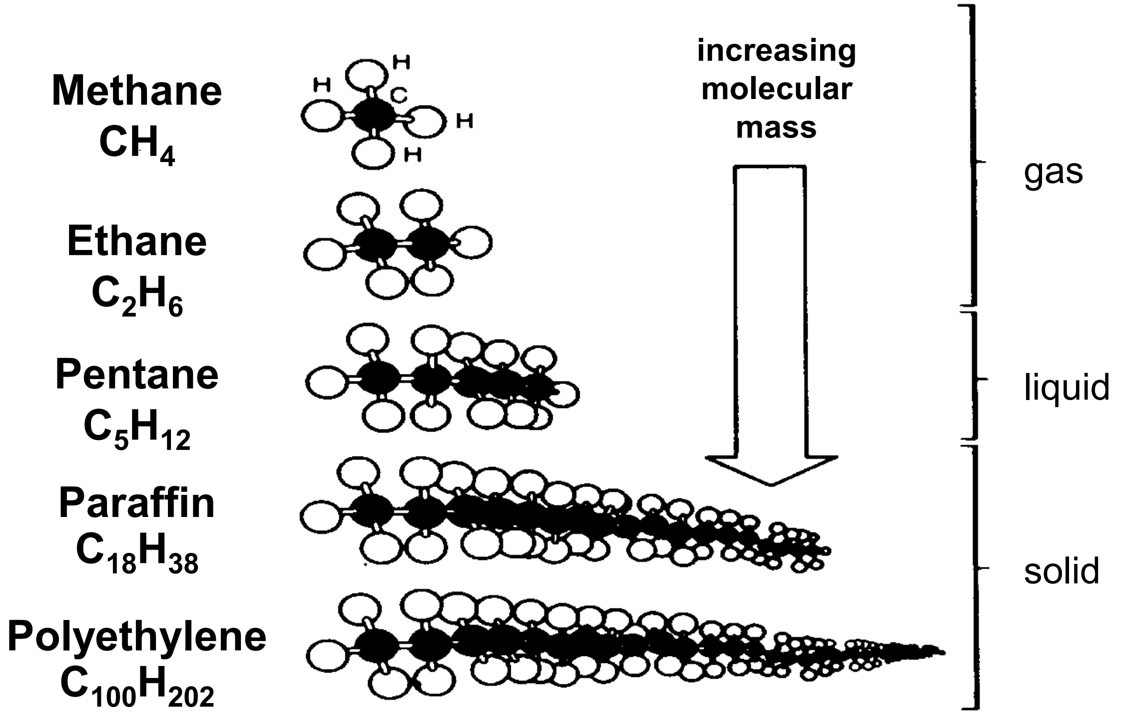
Monomer + Monomer + Monomer + . . $\xrightarrow[\text{Catalyst}]{\text{Heat + Pressure}}$ Polymer (Many Monomers)

$$\begin{array}{ccc} H & & H \\ | & & | \\ C & = & C \\ | & & | \\ H & & H \end{array} + \begin{array}{ccc} H & & H \\ | & & | \\ C & = & C \\ | & & | \\ H & & H \end{array} + \begin{array}{ccc} H & & H \\ | & & | \\ C & = & C \\ | & & | \\ H & & H \end{array} + \cdot\cdot \xrightarrow[\text{Catalyst}]{\text{Heat + Pressure}} \begin{array}{ccccccccccc} H & & H & & H & & H & & H & & H \\ | & & | & & | & & | & & | & & | \\ C & - & C & - & C & - & C & - & C & - & C \\ | & & | & & | & & | & & | & & | \\ H & & H & & H & & H & & H & & H \end{array}$$

Ethylene Gas

"Poly"ethylene

The Chemistry of Plastics: Molecular



Methane
CH_4

Ethane
C_2H_6

Pentane
C_5H_{12}

Paraffin
$C_{18}H_{38}$

Polyethylene
$C_{100}H_{202}$

increasing molecular mass

gas

liquid

solid

Common Polymer/ Material Families

- **Thermoplastics (most widely used; ex. injection molding extrusion**
- **Thermosets (ex. Epoxies, and other Plastics; reactions to form them is terminal so lack ionization potential)**
- **Adhesives (bonding materials)**
- **Elastomers (Stretch and flex)**
- **Metals (steel, aluminum , titanium, etc.)**
- **Ceramics/Glass (vials, bottles, light tubes, etc.)**
- **Bioabsorbables, Cellulosics (polylactics, papers, fibers)**
- **Biologicals, Drugs (Tissue, bone, API, suspensions etc.)**
- **Packaging materials (pouches, trays, lids, etc)**

Note: Material effects can vary if a single process or a repeated process occurs.

The Chemistry of Plastics: Polymer Families

Thermoplastic

- Majority of familiar plastics
- Softens upon heating
- Hardens upon cooling
- Can be reprocessed

Crystalline (Semi)

- Linear alignment of chains
- Harder, less flexible
- Unique melting point

(Ex. PE, PP, PTFE, Polyamide, PEEK, TPU)

Amorphous

- Random structure
- Good clarity
- Broad melt temperature

(Ex. Acrylic, Polycarbonate, PS, PVC, TPU)

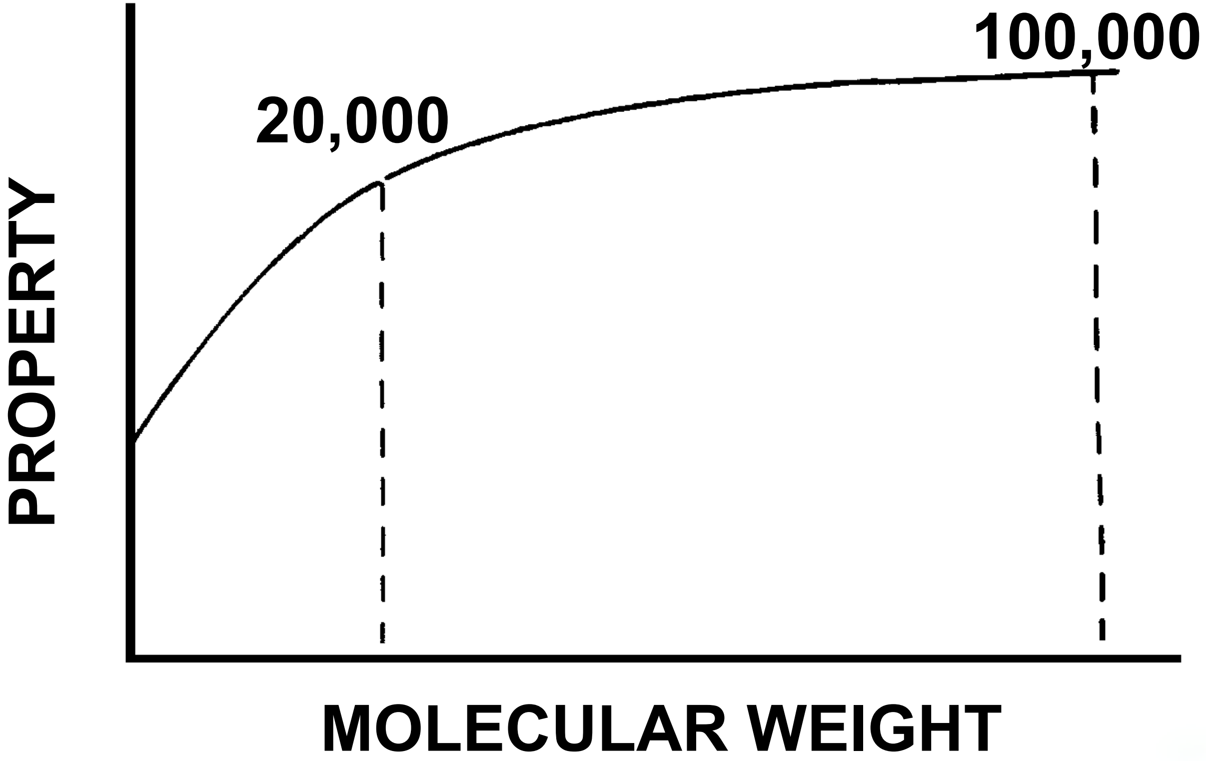
Thermoset

- Hard, strong, rigid
- Will not burn
- Excellent heat resistance

Crystalline *Amorphous*

(Ex. Epoxy, Phenolic, Polyester, Rubber, Silicone, PU)

The Chemistry of Plastics: Physical Properties vs. MW



Ethylene Oxide - Variables

EO processing can seem complex in that we need to control more variables.

- product temperatures, 105 – 145 °F typical. Does not run at ambient temperatures
- dwell and exposure times (hours, not minutes)
- relative humidity, 30 – 100% typical
- pressure and vacuum levels and rates, 1.0 In HgA to Positive pressure.
- gas concentrations, 400 – 800 mg/l
- product configurations/presentation,
- design product for accessibility/allow EO and humidity ingress to vital areas,
- load configurations, chamber specificity
- packaging materials are critical (must be porous)

Ethylene Oxide Material Considerations

- **Unique Materials**
  - Very few significant material issues reported; especially with low numbers of processing cycles.
  - Highly stressed styrenes may craze (as much due to stress as the EO conditions).
  - PVC may blush or distort due to excessive moisture (leaves when moisture does) and heat exposure.
  - Products with moisture and heat concerns
- **Residuals Concerns biggest issue to most**
  - The material's ability to readily absorb and desorb EO is critical
  - Elevated temperature of process aids in residuals being flushed from product.
  - Some materials retain more gas then others.
  - Some products require more aggressive cycles than others
  - Worry of repeat exposure over lifetime of use

EO Materials Considerations

- **Drugs/Biologic Materials**
  - Limited to drugs that can be sterilized as a dry powder
  - Potential degradation due to temperature and humidity must be considered.
  - Collagen (lower temperature cycles) and bone successfully sterilized by ethylene oxide.
  - Harder plastics will have a harder time getting permeation of gas
  - Designs with difficult paths for gas can present problems (ex lubricated stopcocks or stoppers/ grommets.
- Overall physical Issues rare with commonly used materials.

EO

- **Packaging Materials are critical**
  - Design packaging to allow air/gas penetration and removal (gas permeable).
  - Most common example is Tyvek
  - Provide enough permeable surface to allow efficient process.
  - Strong enough to tolerate temperature and pressure extremes (repeated vacuum purges).

General EO Areas of Concern

- Liquids (EG formation)
- Moisture
- Elevated temperature for an extended period of time
- Package restrictions
- Chlorinated cleaners (ECH residuals)
- Bioabsorbables (moisture and heat limitations or considerations)
- Multiple cycles effects may be different than one or a few cycles
- Changing/lowered limitations on EO residuals or general concern on EO residuals for frequently used products

- In general EO is compatible with most polymers used in healthcare products. Optimization of cycle variables is key to most concerns.

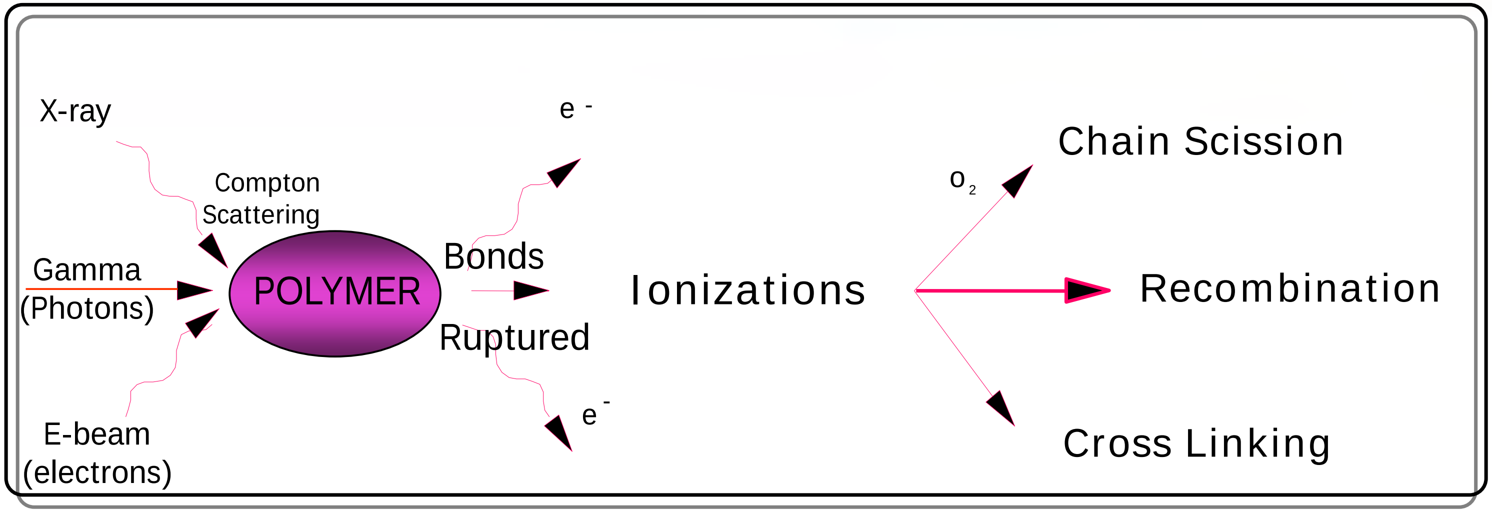
Radiation - Variables

Radiation processing has only **ONE** variable that typically is controlled

- **Time** of exposure (related to dose needed and isotope activity)
- Product temperatures, Sub-zero – 120 °F possible
- Load configurations (typically fixed after once established)

- **Must always consider modification potential on materials**

Radiation Effects on Polymers



- Brittle
- Color
- Odor
- Stiffness
- Softens

- Toxicity
- Chemical inertness
- Melt temperature
- pH (wet/buffered)
- % Crystallinity, Density

Chain Scission vs. Crosslink

After irradiation resultant ionizations combine in a stabilization process to result in:

1) **Recombination** – Polymer bonds are reformed to original state.

2) **Crosslink** - Polymer bonds are joined and a network is formed. Increases tensile strength, rigidity and decreases elongation.

3) **Chain scissioning** – Polymer bonds are terminated and molecular weight and strength is reduced.

- ➢ Materials go through some level of all of these.
  - – Those that crosslink to a greater degree generally are more "stable" in radiation environments.

Color

- In general, at least some discoloration is seen.
  - Crosslinkage creates double bonds that reflect light differently so will discolor.
  - Additives, not polymer maybe what changes color
  - Some will dissipate with time
  - How much discoloration occurs is affected by dose, polymer and formulation.
  - Formulation is most common cause not base polymer alone.
  - Occurs before measurable loss in physical properties.

Odors

- Especially PE, PVC and polyurethane
  - Rancid smell from oils used as plasticizers (ex.soybean and linseed oil)
    - If mechanism of effect is known one may be able to change it, for example modifying amounts of antioxidants, reduced processing temperatures, polymer selection (higher MW).

      Changes needed are usually at the resin formulation level.
    - Elevated post processing temperature conditioning.
    - Gas permeable packaging generally effective.
- Ozone
  - Air trapped in package or outer box
    - Dissipates on opening

Polymer Properties

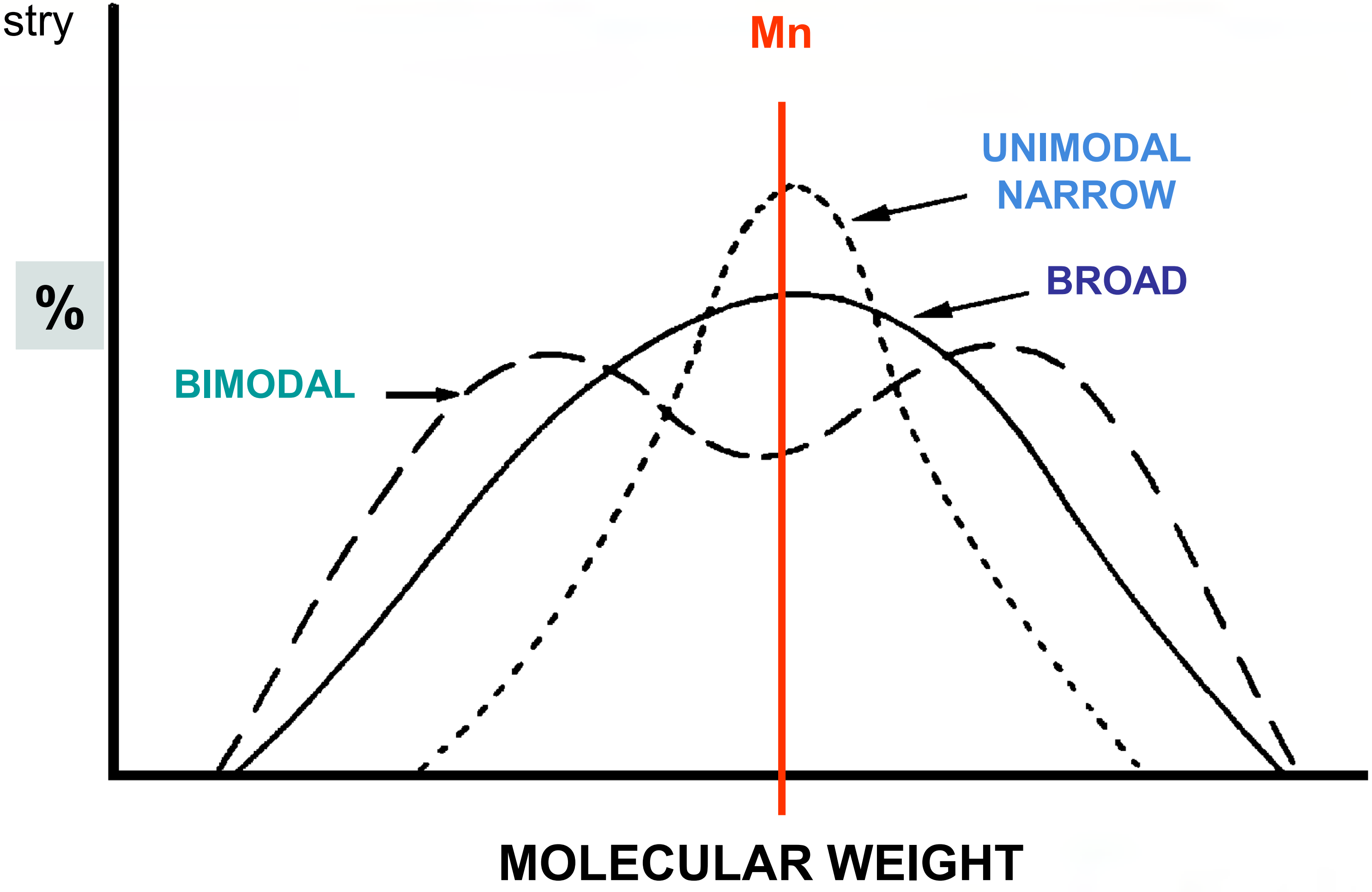
- Resins are really a mixture of things:
  - Additives for Heat tolerance to allow them to survive molding
  - Agents to aid smooth flow in filling and release from a mold
  - Antioxidants
  - Free radical scavengers
  - Plasticizers
  - May have colorants to reduce visible yellowing
  - May be a blend of more than one base plastic
  - They are a sum of parts
  - Two sources or part numbers labeled as the same resin are not necessarily interchangeable.
  - Two base polymers with the same name are not the same and may not behave the same in molding or sterilization. Different suppliers for example will not always behave identically).

Key Points on Chemistry of Plastics: Molecular Weight (MW, Mn)

- **Molecular weight** and **molecular weight distribution** are responsible for many polymer properties observed and are critical to success or failure in a product.
- Molecular weight distribution (MWD) is frequently not noticed. We tend to look at the label for what we want. Reality is there is a distribution of each weight polymer molecule over the range of molecule sizes in a sample. i.e. Broad vs. narrow.
  - Ex. a bottle of a resin of average molecular weight of 10,000 daltons is not pure chains of 10,000. It is a mean or median of the combined mixture in the container.

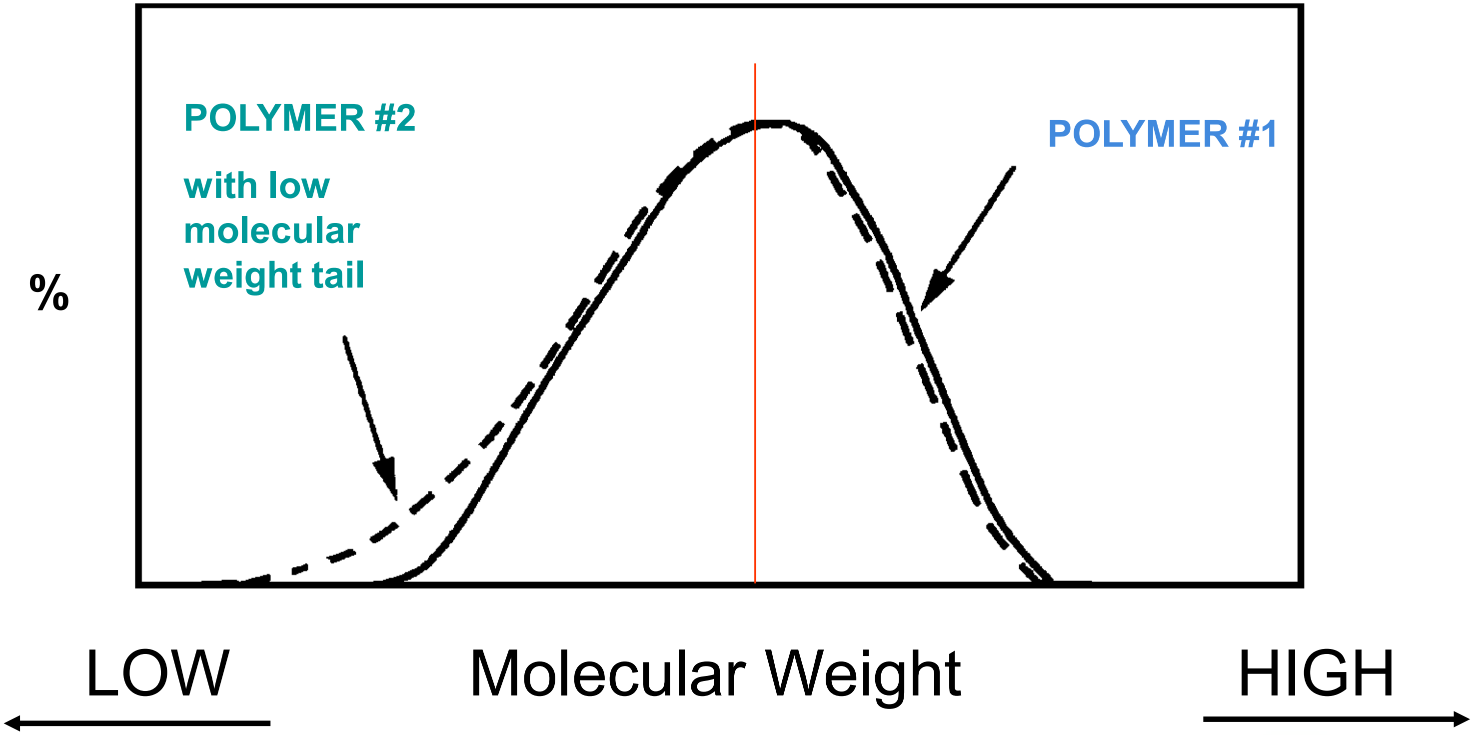
The Chemistry of Plastics: Physical Properties vs. Mw

Polymer Chemistry



The Chemistry of Plastics: Molecular Weight Differences

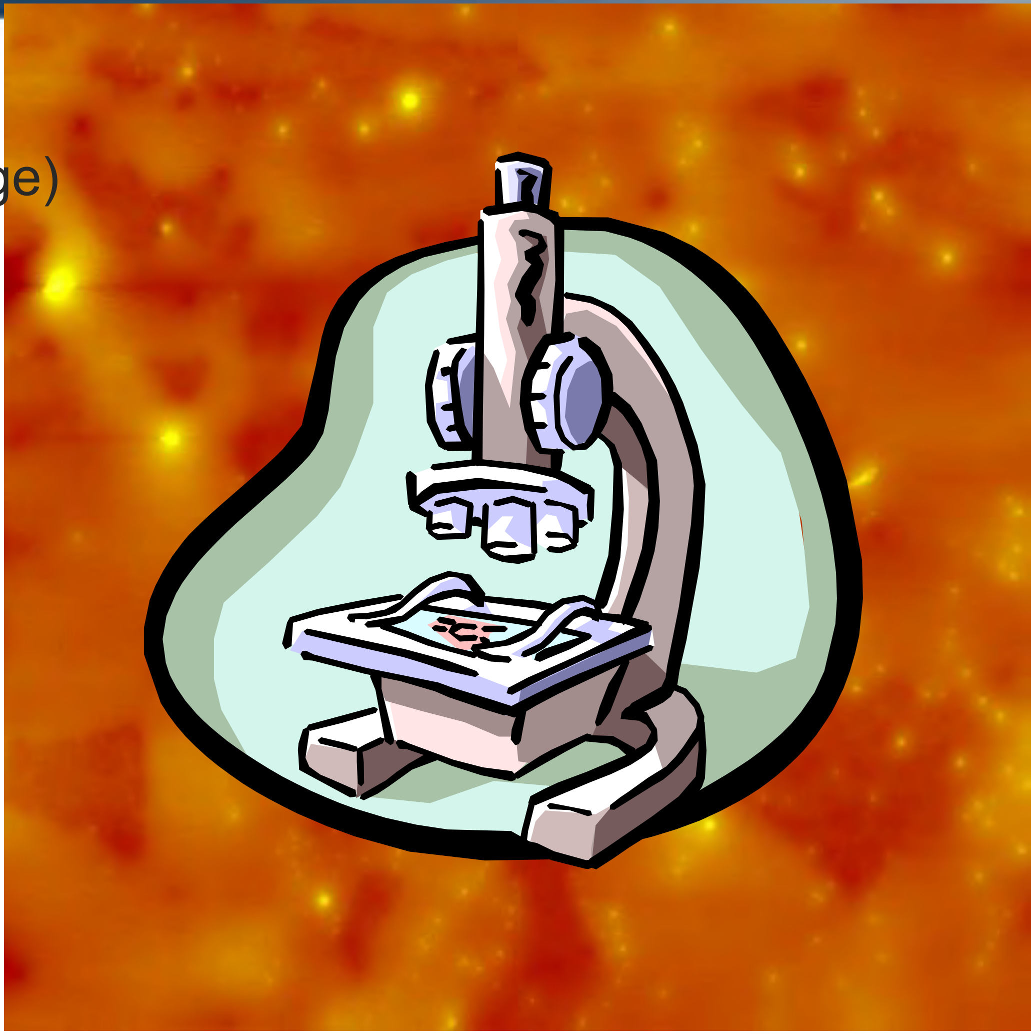
Polymer Chemistry



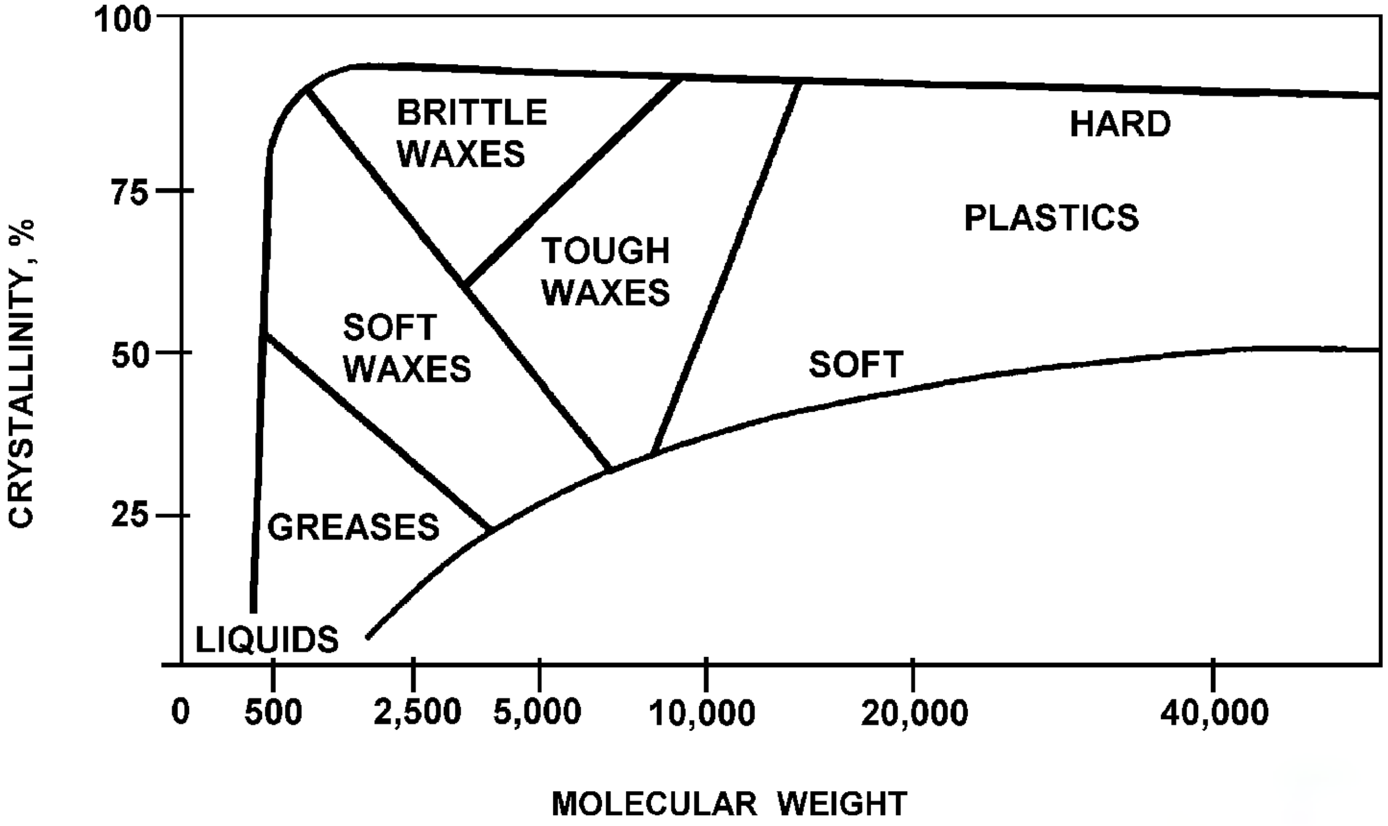
Properties: Crystallinity

Smaller volume (greater shrinkage)

- Increased hardness
- Increased tensile strength
- Greater chemical resistance
- Lower impact strength
- Lower elongation
- Less clarity
- Higher softening temperature (Tm is a point not a range)



The Chemistry of Plastics: Molecular Weight Crystallinity



Radiation Effects (Other than Plastics)

Metals

- Metallic bonds are unique, resulting in minimal ionizations and thus no significant change in properties (gamma)
- Caution in high dose rate modalities (i.e. electron beam)
  - Low specific heat results in elevated temperature rise and stay warm for a while.
  - Check junctures with non metal components
  - High energy (>8 MeV) accelerators can result in displacement of neutrons and creation of measurable short lived radioactive sub-species.

Radiation Effects (Other than Plastics)

Glass

- Significant discoloration is typical.
- Amorphous nature make them insensitive to radiation induced structural change.
- Color can be reduced using cerium laced glass (but limited, rare availability, high cost, long delivery times, negative effect on molds).
- Additives in glass other than silicates also discolor
- Other properties not affected.
- Known; accepted
- Reduces slowly with exposure to light or heat but not back to clear.

Radiation Effects Continued

Drugs, active chemicals

- Extensive post processing validation analysis required.
- Success especially in dry formats.
- Success rarer in liquid formats (due to H+ and –OH ions mobility).
- May have increase success frozen.
- Will be effected by moisture content.

Biological Materials (Tissue, Bone, Serum, Proteins)

- Typically processed in frozen protective formats.
- Some additives are possible (to reduce free radical damage).
- Control of dose requirements (control of bioburden through cleaning procedures).

Radiation Effects

Large surface to mass applications (i.e. packaging)

- films
- coatings
- adhesives
- membranes

Can behave differently than a block of same polymer due to oxygen permeability.

Packaging is significant to a finished product and maintains its sterile claim until use

Most Common Materials Issues- Radiation

- Most medical plastics are durable in radiation
- General Rule: Avoid materials that are **APT** to fail:

Acetals

Propylene

Teflon

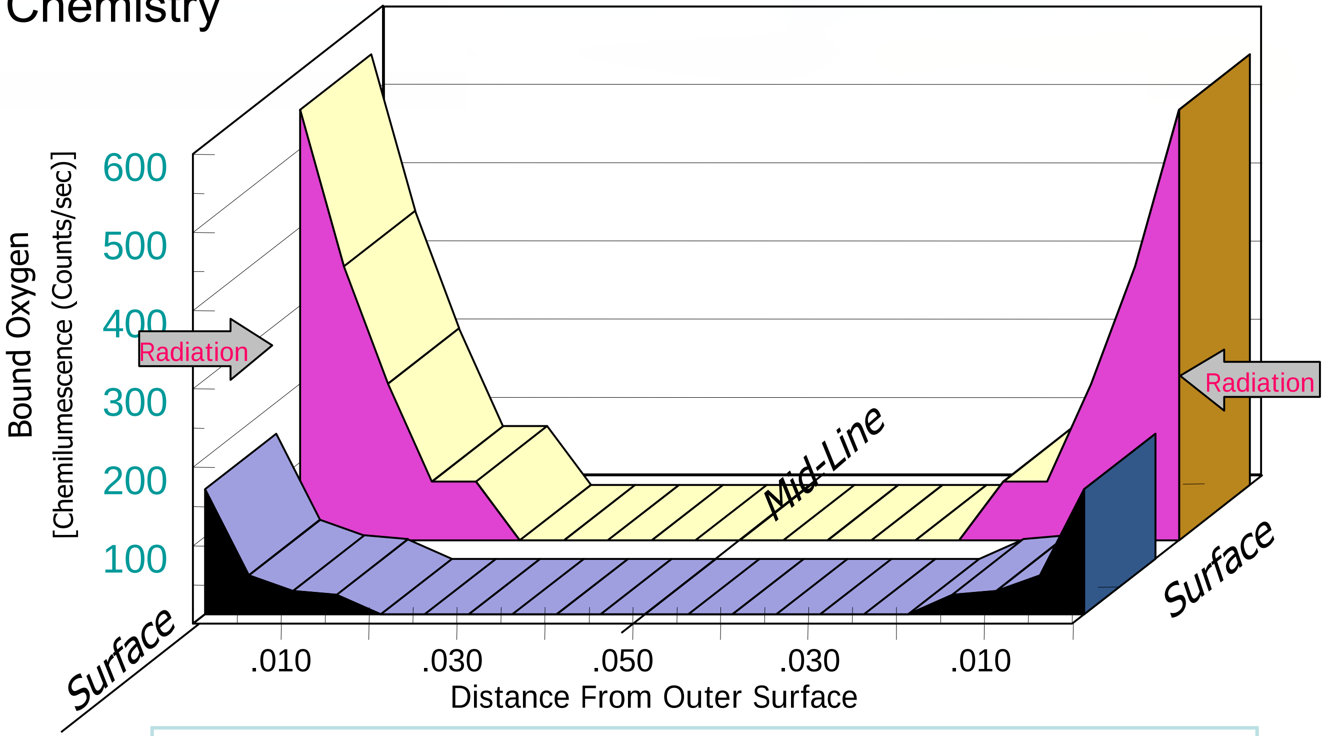
The majority of polymers should be capable of performing to your requirements .

Polypropylene

- Homopolymer/Natural will discolor (yellows).
- Color is precursor to embrittlement
- Starts at doses lower than required for the Sterility Assurance Levels needed for sterilization of most devices.
- Concern for devices more than labware. Alternate SALs can be used in some labware (application dependent/ regulatory dependent).
- Doses over about 20-25 kGy will exhibit significant change.
- If used, select radiation stable grades, which will likely be a co-polymers with a more stable plastic. Will be more expensive than the unstabilized form. Ask for them; not just polypropylene. Tell the supplier you will be using it for a radiation application.

Radiation Induced Degradation of Polypropylene

Polymer Chemistry



🟪 Gamma, Dose Rate = 2 x 10 Gy/hr

⬛ Electron Beam, Dose Rate = 7.2 x 10 Gy/hr

Total Dose = 50 kGy

Teflon

- Especially PTFE
  - Breaks into smaller fragments, even at doses as low as 3-5 kGy
  - FEP better but not great
  - Becomes brittle to the point of grindability to dust
    - Bad if a seal
    - Bad if located at a point where pressure is applied
    - Benefit if used as a lubricant

Acetals

- Delrin and Celcon most common
  - Easy to work with
  - Low cost

- Embrittles badly, cracks and shatters at sterilization doses. No fix, time to think of alternate sterilization modalities, if required or preferred.

Elastomers

- These are the things you want to stay flexible
  - May be man made or natural, thermosets or thermoplastics
  - Most commonly used are the silicones and rubbers (butyl, natural, butadienes), neoprene, EPDM, etc.

  - Natural Rubber, EPDM, urethane, Nitrile, neoprene (especially with an aromatic plasticizer added) are considered very stable.

  - Butyl Rubber is not; tends to be friable and will shed pieces when flexed.

Elastomers

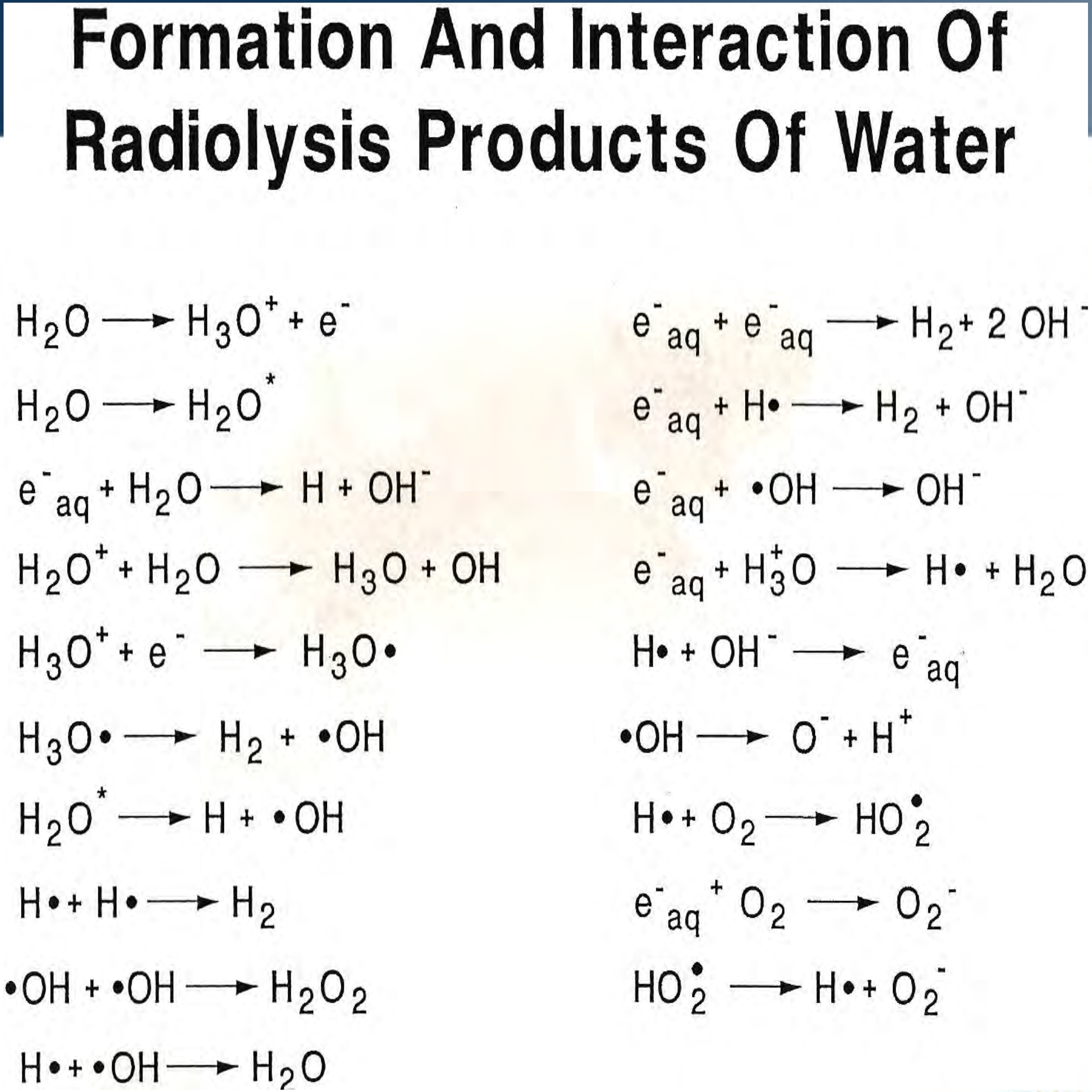
Silicones:

- Radiation stability effected by % fully cured. Catalysts used effect this.
  - Platinum cured Silicone (higher crosslink density) better than Peroxide cured.
  - Phenyl Methyl Silicones more stable then methyl.
  - Read product specification sheets. It will be listed or ask for radiation stable material.

Radiation Effects on Polymers

Ratio scission / crosslink / recombination can be altered by changes in:

- Chemical composition and configurations (layout, side chains or groups)
- Morphology (% crystallinity, MW, density)
- Additives (Radical Scavengers, Anti-oxidants)
- Radiation dose absorbed
- Radiation dose rate (especially in oxygen driven reactions)
- Residual stress (molded-in, assembled-in or by design)
- Environment during irradiation (Temperature, Oxygen/O_3)
- Post-irradiation storage environment (Temperature, Oxygen, Sunlight).



Formation And Interaction Of Radiolysis Products Of Water

$H_2O \longrightarrow H_3O^+ + e^-$

$H_2O \longrightarrow H_2O^*$

$e^-_{aq} + H_2O \longrightarrow H + OH^-$

$H_2O^+ + H_2O \longrightarrow H_3O + OH$

$H_3O^+ + e^- \longrightarrow H_3O\bullet$

$H_3O\bullet \longrightarrow H_2 + \bullet OH$

$H_2O^* \longrightarrow H + \bullet OH$

$H\bullet + H\bullet \longrightarrow H_2$

$\bullet OH + \bullet OH \longrightarrow H_2O_2$

$H\bullet + \bullet OH \longrightarrow H_2O$

$e^-_{aq} + e^-_{aq} \longrightarrow H_2 + 2\ OH^-$

$e^-_{aq} + H\bullet \longrightarrow H_2 + OH^-$

$e^-_{aq} + \bullet OH \longrightarrow OH^-$

$e^-_{aq} + H_3^+O \longrightarrow H\bullet + H_2O$

$H\bullet + OH^- \longrightarrow e^-_{aq}$

$\bullet OH \longrightarrow O^- + H^+$

$H\bullet + O_2 \longrightarrow HO_2^\bullet$

$e^-_{aq}{}^+ O_2 \longrightarrow O_2^-$

$HO_2^\bullet \longrightarrow H\bullet + O_2^-$

The Chemistry of Plastics

OXIDATION

- Decreases crosslinking tendency
- Increases degradation (chain scission)
- Causes peroxide, carbonyl and hydroxyl groups to be formed

Liquids, Gels and Lotions

1. Viscosity changes
2. pH changes
3. Is an active ingredient present and is it's effectiveness changed?
   - If it changes can I live with it or adjust for it?
4. Can an additional component be added to protect the properties desired?
5. Can the properties be modified temporarily and solve or reduce problem? (freezing, lyophilization, dried and then reconstituted for use).

Liquids, Gels, Lotions (Continued)

6. Color
7. Scent
8. Texture
9. Maybe nothing at all
10. Need to evaluate

Active Compounds (APIs)

1. By their very nature Pharmaceutical compounds are very specific and often unique, in function, synthesis and components.

2. Each specific formulation should be checked as early as possible in development. Not just something similar to it.

3. CFR 21 part 310, Sec 310.502 a 11 lists things what are considered to be new drugs. This includes specifically sterilization of new drugs by irradiation.

4. Tests of effectiveness/safety need to be on irradiated material.

Active Compounds (Continued)

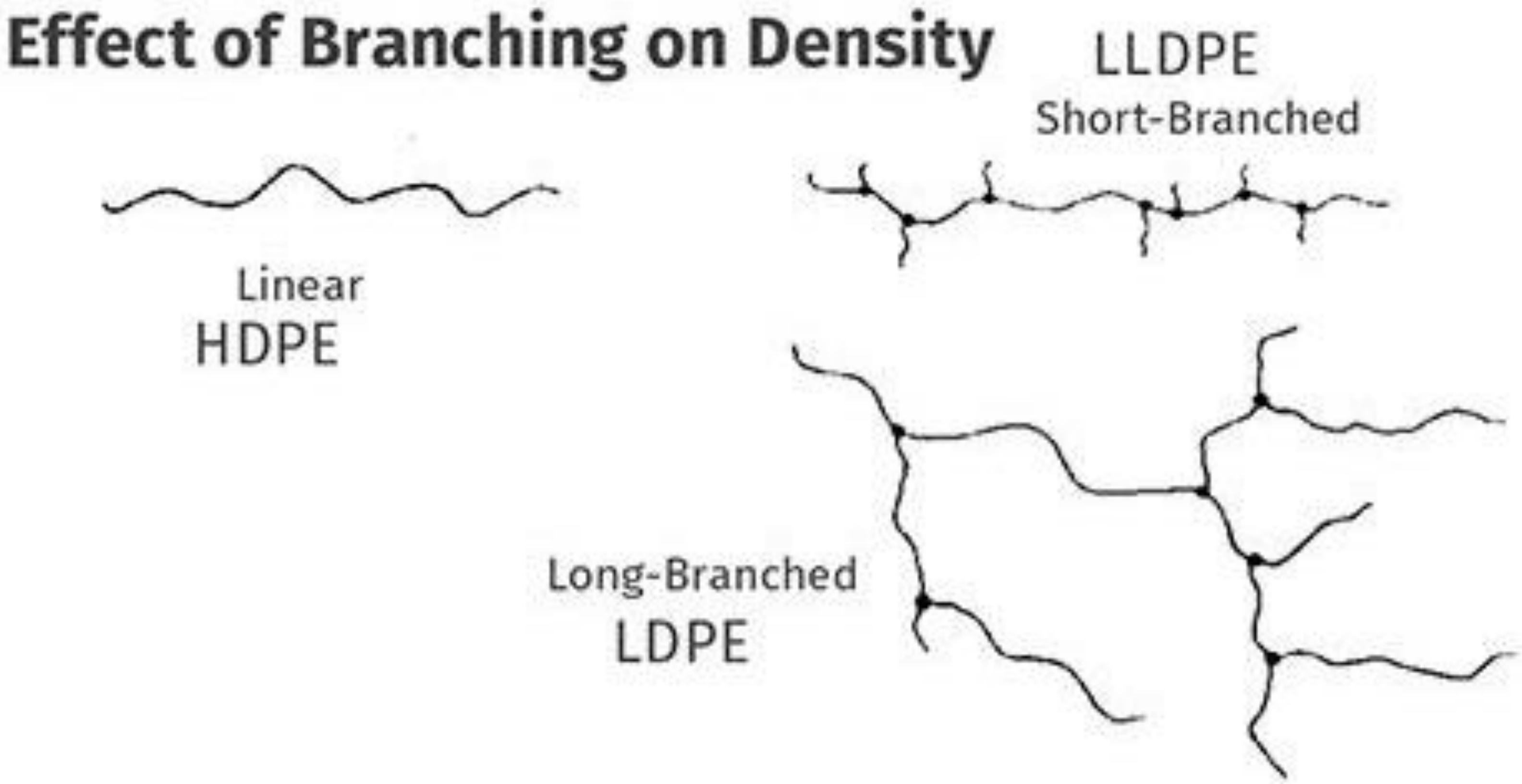
5. Changes that can happen:
    a. Change in polymer length
    b. Conformational changes
    c. Creation of byproducts that are unacceptable or untested
    d. Change in efficacy, potency, color, etc.

6. Maybe nothing at all or minor. Changes may be minor but need to be investigated, documented, etc. Whatever is required by your regulating bodies and your claims
    a. Similar degradation profiles
    b. New degradation products
    c. What are acceptable limits?

Material Guidance for Use with Irradiation

- Start with high molecular weight material when there is an option - Higher molecular weight materials are more radiation resistant than their lower molecular weight relatives.
- Low density materials are more radiation resistant than high density materials
- High Molecular Weight, good load baring capacity, but harder to mold
- Low Molecular Weight, easy to mold but will have more visible knit line (area of weakness)
- High MW Silicone lubricants will tend to pool on irradiation, low MW doesn’t happen but not as good a lubricant.

Example HDPE Vs LDPE



Material Guidance with Irradiation

- Amorphous materials are more radiation resistant than semi crystalline materials
- For semi-crystalline materials, the lower the crystallinity, the greater the radiation resistance. Exception here is very highly crystalline (>95 %) have high resistance (strong, nested compact, mutually reinforced chains)
- Purchase materials with added radioprotectants – antioxidants + heat stabilizers. Commercial resins have these in them or can be formulated to have them. Select the resin # right for your application. Ask the supplier.
- Aromatic materials (containing benzene ring structures) are more radiation resistant than aliphatic materials.

Material Guidance with Irradiation

- Use Narrowest molecular weight distribution possible.
- Materials with low oxygen permeability are better.

Material Guidance with Irradiation

- Polymers that tend to crosslink more than experiencing scission are better.
- Thin films, fibers, adhesives can be more susceptible to oxidation.
- Curing process can effect quality (ex. silicone).
- Critical to Remember: Dose effects are cumulative.
  - Dose delivered at one time vs. the cumulated dose from multiple irradiations will be equivalent.
  - Exceptions may be seen with things highly prone to oxidative scissions ex. large surface to mass or where cumulative exposure to temperature conditions has effect (vs. a cool down between two exposures).

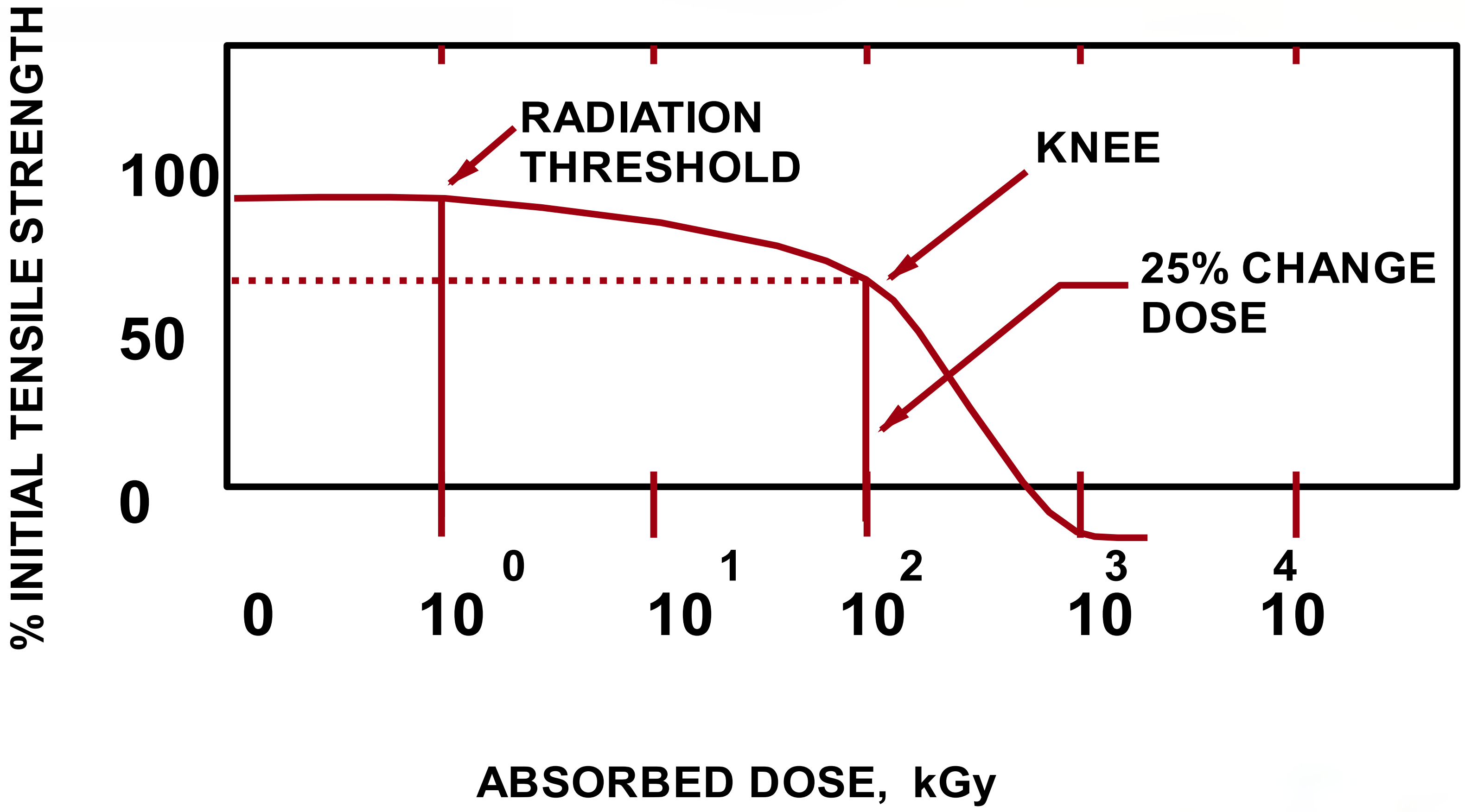
Material Guidance

- Be Cautious of what a literature reference is telling you
  - What is it measuring
  - What specific resin is tested
  - Product design and purpose
  - Test conditions vs. use conditions

  - All can give different answers for something believed to be the same material

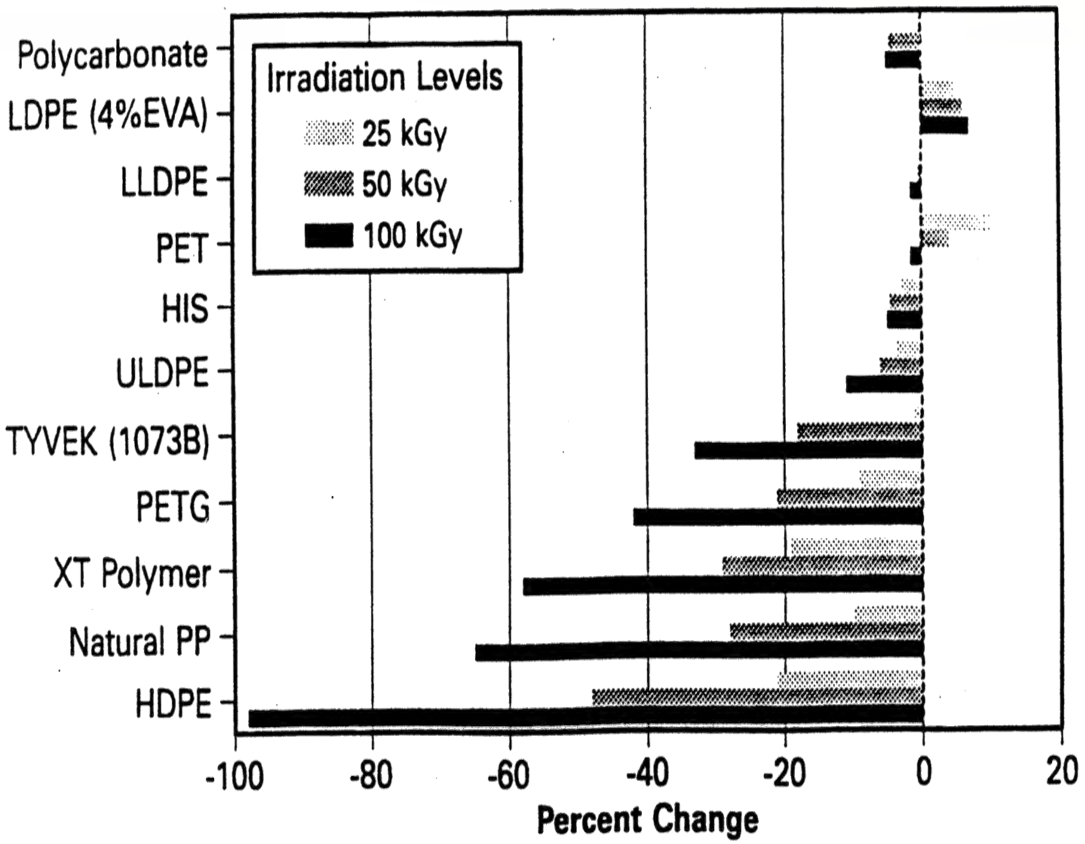
Tensile Strength Vs Dose

Polymer Chemistry



Effect of Radiation on Elongation at Break

Packaging Materials



Material Stabilization for Radiation Applications

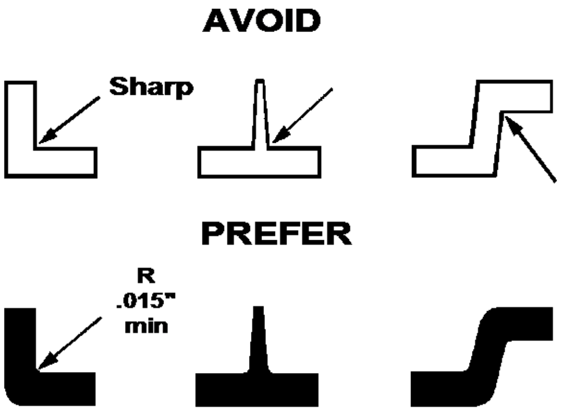
- Co-polymer / alloy vs. homopolymer; pick a good polymer
- Reduce dose (i.e. – reduce Bioburden)
- Mask yellowing with blue/purple tint
  i.e. Ultramarine blue
- Reduce mobility in liquids Ex. Freezing
- Shield from environment (i.e. oxygen, etc.)
  - Inert gas – nitrogen, argon
  - Package design
- Reduce processing abuse molded or assembled in stress.

Part Design and Manufacture

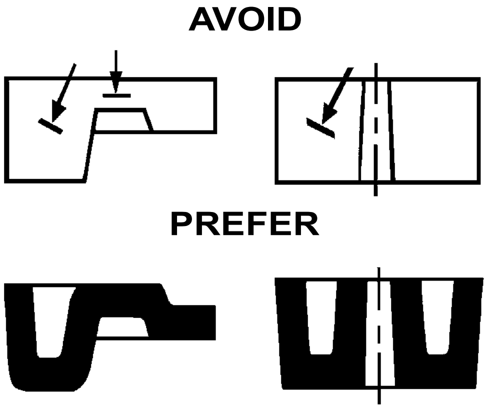
For injection molding, design guidelines include:

- Avoid abrupt thick to thin transitions
- Incorporate generous radii everywhere
- Maintain wall uniformity
- Design molds for fast and easy filling with gates sized and located to minimize material flow pressures and paths. Also design the part for easy ejection to minimize ejection forces and molded-in stresses

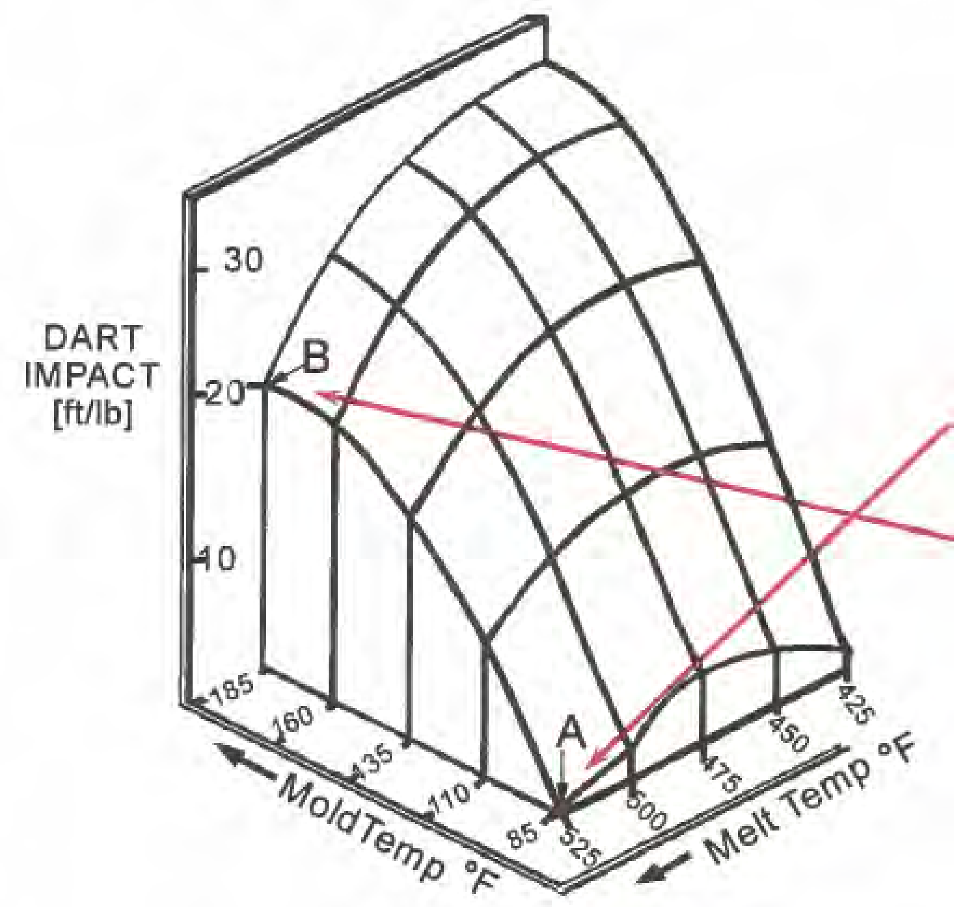
• RADII •



• WALL UNIFORMITY •



Polymer Processing



Graphic demonstrates impact strength increases by 20X in ABS material by simply raising the mold temperature from 85° to 185°

Condition A:
Melt 525°F, Mold 85°F, Impact 1 FT-LB

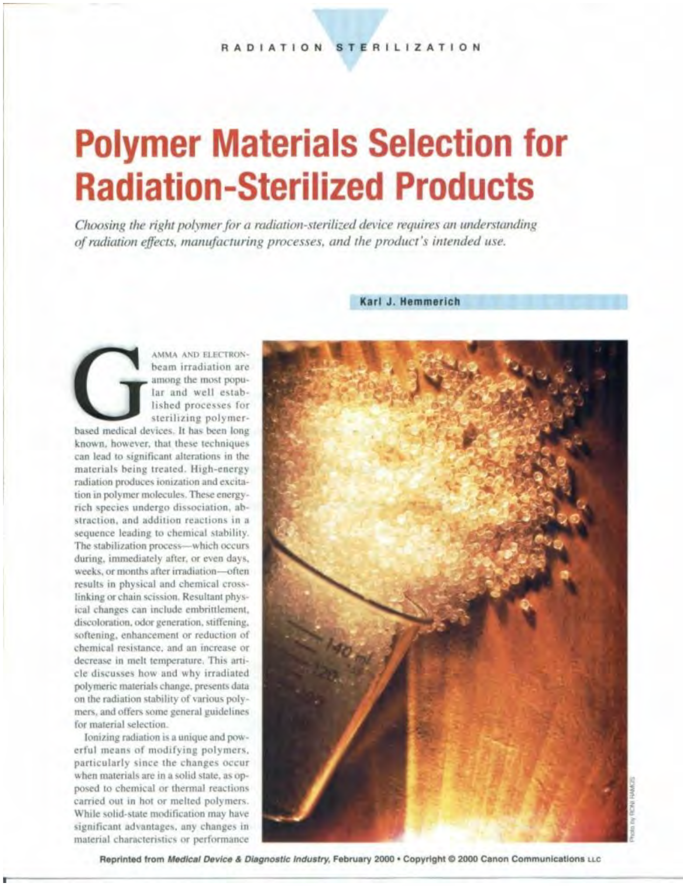
Condition B:
Melt 525°F, Mold 185°F, Impact 20 FT-LB

Qualification Testing Program

- Product Qualification **must be** conducted after exposure to sterilization utilizing “worst case” conditions (EO or Radiation).
- For EO this would be maximum temperature, humidity and cycle time including preconditioning & aeration (Typically 3 cycles)
- For Gamma, E-beam, X-ray this would be a dose greater than or equal to (**≥**) the dose specified as the maximum allowable dose for the product
- Many ASTM methods published. What you test will be based on what you know about failure modes and what you expect the product to do.

Materials References

- AAMI TIR 17
- K.J. Hemmerich, “Polymer Materials Selection for Radiation-Sterilized Products”. http://www.mddionline.com/article/polymer-materials-selection-radiation-sterilized-products
- Ishigaki, J. and Yoshi, F. Radiation Effects on Polymer Materials in Radiation Sterilization of Medical Supplies, Radiation Physics and Chemistry, 39 (6) 527-533,1992.
- Many polymer specific published articles. Not only in healthcare related journals.
- All are guides not guarantees of success in your application.



RADIATION STERILIZATION

Polymer Materials Selection for Radiation-Sterilized Products

Choosing the right polymer for a radiation-sterilized device requires an understanding of radiation effects, manufacturing processes, and the product's intended use.

Karl J. Hemmerich

GAMMA AND ELECTRON-beam irradiation are among the most popular and well established processes for sterilizing polymer-based medical devices. It has been long known, however, that these techniques can lead to significant alterations in the materials being treated. High-energy radiation produces ionization and excitation in polymer molecules. These energy-rich species undergo dissociation, abstraction, and addition reactions in a sequence leading to chemical stability. The stabilization process—which occurs during, immediately after, or even days, weeks, or months after irradiation—often results in physical and chemical cross-linking or chain scission. Resultant physical changes can include embrittlement, discoloration, odor generation, stiffening, softening, enhancement or reduction of chemical resistance, and an increase or decrease in melt temperature. This article discusses how and why irradiated polymeric materials change, presents data on the radiation stability of various polymers, and offers some general guidelines for material selection.

Ionizing radiation is a unique and powerful means of modifying polymers, particularly since the changes occur when materials are in a solid state, as opposed to chemical or thermal reactions carried out in hot or melted polymers. While solid-state modification may have significant advantages, any changes in material characteristics or performance

Photo by RONI RAMOS

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Conclusions

- Sterilization is relatively mild to most polymers used in Healthcare applications. Noted exceptions discussed.
- Most reactions post irradiation are rapid
- Elevated temperatures in transportation should be anticipated as a significant variable. Not just from the sterilization process.
- Take care in choosing materials for the processes you will use, manufacturing as well as sterilization
- Test actual product and package.
- Do Research/ testing before finalizing selections.

Reality

- Ultimately it is the responsibility of a device/product manufacturer to demonstrate that their sterile device meets intended performance requirements and is safe and effective for the time you say it will.
- Information provided in literature, guides, seminars are general guidance intended to be used to initiate a successful materials qualification program; not to replace it.
- It is unacceptable to use this information as the sole rationale for using a material with a given modality.
- Consider what you will do to the product in manufacture and sterilization before selecting a resin.

Reality

- Selecting a resin that is appropriate is easier than fixing a bad one.

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