Material Selection in Flexible Packaging

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Science Driven Vertically-Integrated Flexible Packaging Manufacturer
IMPROVING QUALITY OF LIFE THROUGH ENGINEERED FLEXIBLE MATERIALS

A BILLION PATIENT LIVES
Touched every year with our medical packaging innovations
Primary requirements

**ISO 11607** – Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

- The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, the intended sterilization methods(s), the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials.
The heat-stable layer
Main Requirements

Provides thermal and dimensional stability

Enables the film to be heat-sealed without sticking or stretching

Can provide scuff or abrasion resistance

Provides film stiffness / toughness

Printing substrate (reverse or surface)
<table>
<thead>
<tr>
<th>Oriented Polyester (oPET)</th>
<th>Oriented Nylon (oPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Outstanding dimensional / thermal stability</td>
<td>• Outstanding cut resistance</td>
</tr>
<tr>
<td>• Excellent tensile strength</td>
<td>• Excellent puncture resistance</td>
</tr>
<tr>
<td>• Outstanding abrasion resistance</td>
<td>• Good stress-flex and pinhole resistance</td>
</tr>
<tr>
<td>• Poor stress-flex resistance</td>
<td>• May cross-link and embrittle when irradiated (high doses of $\gamma$ or e-beam)</td>
</tr>
<tr>
<td>• Prone to dart tearing</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cast Nylon</th>
<th>Oriented Polypropylene</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Outstanding durability</td>
<td>• Good dimensional and thermal stability (less than oPET andnylons)</td>
</tr>
<tr>
<td>• Outstanding stress-flex / pinhole resistance</td>
<td>• Not suitable for gamma or e-beam irradiation (severe degradation and embrittlement)</td>
</tr>
<tr>
<td>• Outstanding blunt puncture resistance</td>
<td>• Excessive shrinkage in retort applications (compared to oPET)</td>
</tr>
<tr>
<td>• Difficult to cut</td>
<td></td>
</tr>
<tr>
<td>• May cross-link and embrittle when irradiated (high doses of $\gamma$ or e-beam)</td>
<td></td>
</tr>
<tr>
<td>Tyvek®</td>
<td>Paper</td>
</tr>
<tr>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td>- Breathable, uncoated or with appropriate coatings</td>
<td></td>
</tr>
<tr>
<td>- Outstanding strength</td>
<td></td>
</tr>
<tr>
<td>- Outstanding durability</td>
<td></td>
</tr>
<tr>
<td>- Outstanding tear resistance</td>
<td></td>
</tr>
<tr>
<td>- Fair thermal stability</td>
<td></td>
</tr>
<tr>
<td>- Fair dimensional stability</td>
<td></td>
</tr>
<tr>
<td>- Breathable, uncoated or with appropriate coatings</td>
<td></td>
</tr>
<tr>
<td>- Thermally stable</td>
<td></td>
</tr>
<tr>
<td>- Add bulk</td>
<td></td>
</tr>
<tr>
<td>- Excellent printing surface</td>
<td></td>
</tr>
<tr>
<td>- Particulate can be a concern</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HDPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Fill this one in...</td>
</tr>
</tbody>
</table>
The barrier layer
Main requirements

Provide barrier (either in or out) to:

- Oxygen
- Water Vapor
- Aroma
- Chemical
- UV
- Microbial
- Others
A barrier taxonomy

Barrier films
  ◦ Barrier proportional to film thickness

Barrier coatings
  ◦ Barrier proportional to coating thickness

Combination of films/coatings
The Historical Solution

Aluminum Foil
- Virtually impervious to moisture and gas (> 1 mil / 25 µm thickness)
- Well understood with long history
- Opaque
- Limited formability

<table>
<thead>
<tr>
<th>Foil Gauge (in / µm)</th>
<th>Typical Count (per ft²)</th>
<th>Typical Maximum Count (per ft²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00025 / 6.4</td>
<td>41</td>
<td>320</td>
</tr>
<tr>
<td>0.00030 / 7.6</td>
<td>20</td>
<td>60</td>
</tr>
<tr>
<td>0.00035 / 9.0</td>
<td>12</td>
<td>40</td>
</tr>
<tr>
<td>0.00050 / 13</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>0.00070 / 18</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>0.0010 / 25</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Seal ingress

When the film barrier is that good, ingress through the seals can impact the overall package barrier performance.
EVOH

Excellent Oxygen Barrier
- 0.006 - 0.12 cc·mil/100 in2·day

Excellent odor/aroma barrier

Thermoformable
COC

Good moisture barrier
- 0.2 g·mil/100 in²·day

Enhances stiffness

Excellent clarity

Thermoformable

Heat resistant grades available
PCTFE

Excellent moisture barrier
- Aclar 22A: 0.038 g·mil/100 in²·day
- Aclar UltRx, SupRx: 0.016 g·mil/100 in²·day
- Aclar Flex: 0.010 g·mil/100 in²·day

Inert

Excellent clarity

Thermoformable
Nanocomposites

Polymer structures containing fillers (e.g. clays)
  ◦ Generally blended into nyons and polyolefins
  ◦ Can also be blended into coatings

Filler separates into tiny high aspect ratio platelets

Improved mechanical properties

Increased oxygen and gas barrier

Essentially increases the “apparent thickness” of the film
Metallization

Aluminum metallization

- Good oxygen and moisture barrier

<table>
<thead>
<tr>
<th>Material</th>
<th>O$_2$TR (cc/100 in$^2$·day)</th>
<th>WVTR (g/100 in$^2$·day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metallized PET (standard)</td>
<td>0.1</td>
<td>0.05</td>
</tr>
<tr>
<td>Metallized PET (high optical density)</td>
<td>0.04</td>
<td>0.03</td>
</tr>
<tr>
<td>Metallized PET (high barrier)</td>
<td>&lt;0.02</td>
<td>&lt;0.02</td>
</tr>
</tbody>
</table>
PVdC

Good oxygen and moisture barrier

Good aroma/flavor barrier

Widely used and well understood

Contains chlorine

- Specialized equipment to apply
- Extra diligence required during incineration

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<tr>
<th>Material</th>
<th>O$_2$TR (cc/100 in$^2$·day)</th>
<th>WVTR (g/100 in$^2$·day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVdC-coated PET</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>PVdC-coated OPP</td>
<td>1.3</td>
<td>0.3</td>
</tr>
<tr>
<td>PVdC-coated Nylon 6</td>
<td>0.5</td>
<td>0.65</td>
</tr>
</tbody>
</table>
PVOH

Polyvinyl alcohol

Excellent oxygen barrier
  - PVOH-coated PET
    - 0.2 cc/100 in²·day
  - PVOH-acrylic-coated OPP
    - 0.02 cc/100 in²·day

Barrier dependent upon coating thickness

Moisture sensitive
## ClearFoil® - SiO$_x$ and Al$_2$O$_3$ barrier coatings

### Product Name | Barrier Coating | Retort/Autoclave | Hot-fill/Low Temp. Pasteurization | Gamma | EtO | MV Barrier (g/100in$^2$/24 hrs) | O$_2$ Barrier (cc/100in$^2$/24 hrs) | MV Barrier (g/m$^2$/24 hrs) | O$_2$ Barrier (cc/m$^2$/24 hrs) | Relative Cost ($-$$$)
---|---|---|---|---|---|---|---|---|---|---
ClearFoil® Z | Al$_2$O$_3$ | ● | ● | ● | 0.0008 | 0.0008 | 0.012 | 0.012 | $$$
ClearFoil® X | Al$_2$O$_3$ | ● | ● | ● | 0.003 | 0.004 | 0.047 | 0.06 | $$
ClearFoil® M | Al$_2$O$_3$ | ● | ● | ● | 0.02 | 0.02 | 0.31 | 0.31 | $$
ClearFoil® V | Al$_2$O$_3$ | ● | ● | ● | 0.02 | 0.05 | 0.31 | 0.78 | $
ClearFoil® V2 | Al$_2$O$_3$ | ● | ● | ● | 0.05 | 0.002 | 0.85 | 0.037 | $$
ClearFoil® A | SiO$_x$ | ● | ● | ● | 0.04 | 0.04 | 0.62 | 0.62 | $$$
ClearFoil® E | Al$_2$O$_3$ | ● | ● | ● | 0.06 | 0.02 | 1.0 | 0.3 | $
ClearFoil® D | Al$_2$O$_3$ | ● | ● | ● | 0.06 | 0.06 | 0.93 | 0.93 | $
ClearFoil® H | Al$_2$O$_3$ | ● | ● | ● | 0.13 | 0.13 | 2.0 | 2.0 | $

* Suitability for retort and gamma sterilization is dependent on sealant chemistry

Oxygen barrier was tested at 0% relative humidity and 73°F. Moisture vapor was tested at 100% humidity and 100°F. Barrier numbers represent typical values and are not limiting specifications.

ClearFoil is a registered trademark of Rollprint Packaging Products, Inc.
ClearFoil® - SiO$_x$ and Al$_2$O$_3$ barrier coatings

![Graph showing g/100in²•day for 1 & 2 mil Foil and ClearFoil® X after 0 and 20 cycles.](image)
The sealant layer
Sealants overview

Weld (or lock-up) seals – seals like materials together
  ◦ Films

Peelable seals – controlled material incompatibilities
  ◦ Adhesive peel
  ◦ Cohesive peel
  ◦ Films
  ◦ Heat seal coatings
## Polyethylene

### Polyethylenes:

<table>
<thead>
<tr>
<th>PE type</th>
<th>Density (g/cm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Low Density Polyethylene (VLDPE)</td>
<td>0.890 - 0.915</td>
</tr>
<tr>
<td>Low Density Polyethylene (LDPE)</td>
<td>0.915 - 0.925</td>
</tr>
<tr>
<td>Medium Density Polyethylene (MDPE)</td>
<td>0.926 - 0.940</td>
</tr>
<tr>
<td>High Density Polyethylene (HDPE)</td>
<td>0.941 - up</td>
</tr>
</tbody>
</table>
Polyethylene

Linear (e.g. LLDPE, LMDPE)
- Higher melt points (15 - 25°F higher)
- Better chemical resistance
- Better durability
  - Impact strength
  - Puncture resistance
- Stronger seals (to itself)
Polyethylene

Metallocenes (e.g. mLLDPE, mPE)
- Single-site metallocene catalyst yields lower molecular weight distribution than traditional multi-site catalyst
- Low extractables
- Lower seal initiation temperature
- Better hot tack
- Superior tensile strength
- Higher elongation
- Better durability
  - Puncture
  - Impact
Polyethylene Copolymers

Ethylene vinyl acetate (EVA)
- Most range from 2% - 24% vinyl acetate
- As VA content increases:
  - Sealing and softening temperature decrease
  - Impact strength increases
  - Flexibility increases
  - Stress-flex properties increase
- Less crystalline than equivalent LDPE
- Less chemical resistance than LDPE

Ethylene-Methyl Acrylate (EMA)
Ethylene-Ethyl Acrylate (EEA)
Ethylene Acrylic Acid (EAA)
Polypropylene

Homopolymer grades
- High melt point (Approx. 330°F)
- Excellent temperature resistance
- Used for autoclave sterilization
- Good chemical resistance
- More stiff and brittle than PE
- Less crystalline than PE

Random copolymer grades
- Contain 1 - 5% ethylene molecules randomly inserted into the polymer backbone
- Lower melting point
- More flexible
- Better impact resistance
- Easier to heat seal than homopolymer PP
- Better performance at cold temperatures
Ionomers (Surlyn)

Derived from ethylene-methacrylic acid copolymers

- Zinc cation
  - Best for product high in alcohol or water content
  - Provide adhesion to foil

- Sodium cation
  - Better hot tack
  - Better resistance to oil and grease

- Low sealing temperature
- High seal strength
- Good hot tack
- Ability to seal through contaminants
- Good oil and grease resistance
- Good impact strength
- Good puncture resistance
- Excellent formability
Amorphous Polyester (APET)

Excellent chemical resistance

Chemically “clean”

High temperature resistance
  ◦ Dry heat sterilization

Seals to polar materials
Peelable seals - background

Adhesive Peel
- Poor Seal Indicator
- Sensitive to Operating Variation
Peelable seals - background

Cohesive Peel
- Seal Indicator
- Wider Operating Window
- Stringing
Peelable seals - background

Delamination (Interlaminar)
- Webbing/Stringing
- Variable Seal Strength
Heat Seal Coatings

Vinyl acetate (VA)
Ethylene inter-polymers
Polypropylene (PP)
Polyester (APET)
Ionomer (Surlyn)
Polybutylene

Cohesive peel

Control seal strength with chemistry

Can be films or extrusion coatings
Variation of seal strength with polybutylene sealant thickness

Seal strength (g/in) vs. Polybutylene sealant thickness (mil)

- 0.75 mil
- 1.25 mil
- 2.00 mil
Polybutylene

Seal initiation temperature of non-aged film lower than aged film
Aged seal strength lower than non-aged seal strength

Effect of aging on polybutylene seal strength

Film aged before sealing
Effect of seal aging
Alternate peelable chemistries

Seal strength largely independent of temperature, pressure, and dwell

WYSIWYG (What You See Is What You Get)

Bright white seal indicator without stringing

Seal strength controlled by chemistry
Much flatter seal strength profile as a function of temperature, compared to polybutylene-based peelable sealants.
Sealed to LDPE

Seal strength can be tailored by adjusting the sealant chemistry
Making the Best Choice

Product to be packaged
Type of sterile barrier system
Packaging equipment
Sterilization method
Width “sweet spot”
Volume