Materials and Common Failure Modes in Flexible Packaging

Jerry McGinnis and Lyndsey McMillan
Materials Selection

PACKAGE FORMAT
- Stand-Up Pouch
- Rigid Container
- Pillow Pack
- Product Size
- Flat Bottom Bag
- Peggable
- Semi-Rigid

STERILIZATION
- Radiation
- Autoclave
- Sterilant Gas

CONVERTING
- Heat Seal
- Registration
- Dead Fold
- Fin Seal
- Forming
- COF
- Lap Seal
- Cold Seal
- Speed
- Stiffness

PRODUCT REQUIREMENTS
- H₂O Barrier
- Autoclave
- Barrier

CONVENIENCE FEATURES
- Easy Peel
- Easy Tear
- Clarity
- Printing
- Metallic
- Re-closable
- Pigmented

PACKAGE DISTRIBUTION
- Shelf Life
- Seal Strength
- Compression Strength
- Puncture Resistance
- Burst Strength
- Flex Crack Resistance
- Abrasion Resistance

PACKAGING MATERIAL SPECIFICATION

ECONOMICS & LOGISTICS
- Unit Volume
- Lead Time
Agenda

Porous Materials
- Porous Materials
- Porous Material Defects and Failures
  - QA Testing
  - Common Failure Modes

Films and Laminates
- Laminates for Pouches
- Coextruded Films for Horizontal Form, Fill, & Seal (HFFS)
- Film/Laminate Material Defects and Failures
  - Defects & Common Failure Modes
  - Analytical Methods
Role of Porous Substrate

• **Purpose**
  – To allow for easy transfer of gaseous sterilant (typically Ethylene Oxide) and flushing gases in and out of a sealed package
  – To prevent post-sterilization contamination

• **Requirements:**
  – Porosity/breathability
  – Temperature/moisture resistance
  – Package burst strength
  – Microbial barrier

• **Applications:**
  – Pouches, lids, header strips
Critical Tests - Porosity

- Bendtsen Porosity (ISO 5636-3) – determines the air permeance of a substrate by measuring resistance to airflow through the material.
Critical Tests – Microbial Barrier

- ASTM F1608 Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
  - Controlled flow rate through material
  - Inject aerosolized spores of bacillus subtilis into chamber
  - Challenged with ~1,000,000 spores
  - Collect spores which pass through and incubate
  - Count colony forming units (CFU)
  - Report results in log reduction value (LRV)

<table>
<thead>
<tr>
<th>Filtration Efficiency</th>
<th>LRV</th>
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<tbody>
<tr>
<td>99.9999%</td>
<td>6</td>
</tr>
<tr>
<td>99.999%</td>
<td>5</td>
</tr>
<tr>
<td>99.99%</td>
<td>4</td>
</tr>
<tr>
<td>99.9%</td>
<td>3</td>
</tr>
<tr>
<td>99.0%</td>
<td>2</td>
</tr>
<tr>
<td>90.0%</td>
<td>1</td>
</tr>
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</table>
Uncoated Products
CPT™ (Clean Peel Transfer):

- Engineered for sealing to uncoated Tyvek® or paper
- Provides a “controlled peel”
- Consistent, reproducible seal quality
- No fiber tear/lift from Tyvek® or paper
- Clean, white sealant transfer
- Can be applied to different product types (laminates or coextruded films)
- Offers economical total package system (no heat seal coating)

Tyvek® is a registered trademark of DuPont
CPT™ System

Uncoated Tyvek® / CPT™ film

• Advantages:
  – Lower cost than coated Tyvek®
  – Good durability

• Disadvantages:
  – Lighter seal transfer than heat seal coated Tyvek®
  – Potential for Tyvek® splitting
  – Narrow seal window
  – Potential for transparentization of Tyvek®
  – CPT™ films have slightly more haze

Tyvek® is a registered trademark of DuPont
Uncoated Options

Paper / Film Systems:

- Non-reinforced paper: PaperLock™ CP
- Advantages:
  - Low cost
- Disadvantages:
  - Transfer, fiber tear, seal strength, seal window
- Typical applications:
  - Syringes, pipettes
- More popular in Latin America and Europe
CPT™ System

Cohesive Split of CPT™ Layer

Provides Tamper Evidence and Consistent Peel Force
Coated Products
Coating Advantages and Limitations

Advantages of Heat Seal Coatings
• Low seal initiation temperature and wide sealing range
• Provides excellent white seal transfer upon opening
• Seals to a wide variety of materials including:
  – PETG, PC, PS, PVC, EVA, PE

Limitations of Heat Seal Coatings
• Increases material cost
• Potential for product contact to abrade coating
Seal Transfer

Provides visual evidence that seal has not been compromised

– Solid
– Opaque
Heat Seal Coatings

**Ingredients:**
- EVA based dispersions – provide hot tack, bond strength, and low seal initiation temperature
- Tackifier resins – provide bond strength, transfer
- Waxes – provide transfer, smooth peel, and wider seal window
- Proprietary chemical additions to facilitate proper agglomeration

**Preparation:**
- Proprietary mixing process
- Mechanical modification using a mill

Applied to 100% of surface using an air knife coater
Use of an air jet to doctor off excess coating evenly across the surface
Air Knife Coating
Benefits of Air Knife Coating

**Air Knife** – applies an even amount of coating over an uneven surface

**Contact Coating** – applies an uneven amount of coating over an uneven surface

*Tyvek® is a registered trademark of DuPont*
BHP Coatings
Choosing the Correct System

- Critical to look at each application to determine the best porous product

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>DESCRIPTION</th>
<th>STRENGTH/DURABILITY</th>
<th>MICROBIAL BARRIER</th>
<th>POROSITY</th>
<th>TRANSFER</th>
<th>SEAL STRENGTH</th>
<th>SEAL WINDOW</th>
<th>HOT TACK</th>
<th>CREEP RESISTANCE</th>
<th>COST</th>
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<tbody>
<tr>
<td>PaperLock™ CP</td>
<td>Uncoated Non-Reinforced Paper</td>
<td>Fair</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Fair</td>
<td>Good</td>
<td>Fair</td>
<td>Good</td>
<td>$</td>
</tr>
<tr>
<td>PS45A</td>
<td>Coated Non-Reinforced Paper</td>
<td>Fair</td>
<td>Good</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Best</td>
<td>Best</td>
<td>Better</td>
<td>$$</td>
</tr>
<tr>
<td>PS75</td>
<td>Coated Reinforced Paper</td>
<td>Better</td>
<td>Good</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Best</td>
<td>Best</td>
<td>Better</td>
<td>$$$</td>
</tr>
<tr>
<td>Uncoated Tyvek®/CPT</td>
<td>Uncoated Tyvek®</td>
<td>Best</td>
<td>Better</td>
<td>Better</td>
<td>Fair</td>
<td>Good</td>
<td>Fair</td>
<td>Fair</td>
<td>Better</td>
<td>$$$$</td>
</tr>
<tr>
<td>CR27/ Tyvek®</td>
<td>Coated Tyvek®</td>
<td>Best</td>
<td>Better</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Better</td>
<td>Good</td>
<td>Better</td>
<td>$$$$</td>
</tr>
<tr>
<td>SBP2000/Tyvek®</td>
<td>Coated Tyvek®</td>
<td>Best</td>
<td>Better</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Better</td>
<td>Good</td>
<td>Better</td>
<td>$$$$</td>
</tr>
<tr>
<td>SBP3A/Tyvek®</td>
<td>Coated Tyvek®</td>
<td>Best</td>
<td>Better</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Better</td>
<td>Best</td>
<td>Better</td>
<td>$$$$</td>
</tr>
</tbody>
</table>
Failure Modes & Testing – Porous Materials
QA Tests

- **Coat Weight**
  - Measure directly as well as using NDC for continuous coat weight measurements

- **Porosity**
  - Can adjust with dryer conditions

- **Anchorage**
  - Can adjust with dryer conditions

- **Seal Strength**
  - Dependent on coating formula
  - Look at batch sheets if there are issues
  - Can use IR to look at ratios of ingredients
Coating Process Inspection System

Vision system to flag defects
– Holes in Web
– Coating chunks
Puncture - Tyvek®

Lid viewed from the outside of the package

Lid viewed from the inside of the package

*Tyvek® is a registered trademark of DuPont*
Flex Crack - Paper

Paper flex crack in seal area
Abrasión - Tyvek®

Tyvek® es un registro de marca de DuPont
Contamination
Seal Creep – Tray and Pouch
Films & Laminates
Films & Laminates

**Laminates for Pouches**
- Exterior materials
- Barrier materials
- Sealant materials

**Horizontal Form, Fill, & Seal (HFFS) Rollstock**
- Coextruded Films
Laminates for Pouches – Exterior Layers

Role of the Exterior Layer

- Dimensional Stability
- Heat Resistance
- Stiffness
- Tear Propagation
- Coefficient of Friction
- Optical Properties
  - Clarity
  - Gloss
  - Opacity
- Mechanical Properties
  - Puncture Strength
  - Abrasion & Flex Crack Resistance
- Barrier

Common Exterior Materials

- BOPET (Biaxially Oriented Polyester)
- BOPA (Biaxially Oriented Polyamide)
- BOPP (Biaxially Oriented Polypropylene)
- Paper
# Laminates for Pouches – Exterior Layers

<table>
<thead>
<tr>
<th></th>
<th>BOPET</th>
<th>BOPA</th>
<th>BOPP</th>
<th>Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensional Stability</td>
<td>Excellent</td>
<td>Excellent</td>
<td>Good</td>
<td>Excellent</td>
</tr>
<tr>
<td>Heat Resistance</td>
<td>up to 190 C</td>
<td>Up to 190 C</td>
<td>up to 150 C</td>
<td>up to 200 C</td>
</tr>
<tr>
<td>Puncture Strength</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Abrasion Resistance</td>
<td>Good</td>
<td>Best</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Flex Crack Resistance</td>
<td>Good</td>
<td>Better</td>
<td>Best</td>
<td>Poor</td>
</tr>
<tr>
<td>Relative Moisture Barrier</td>
<td>Fair</td>
<td>Fair</td>
<td>Best</td>
<td>Poor</td>
</tr>
<tr>
<td>Relative Oxygen Barrier</td>
<td>Good</td>
<td>Best</td>
<td>Fair</td>
<td>Poor</td>
</tr>
<tr>
<td>Gamma Sterilisation</td>
<td>Stable</td>
<td>Some</td>
<td>Significant</td>
<td>Stable</td>
</tr>
<tr>
<td>degradation</td>
<td></td>
<td>degradation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative Cost</td>
<td>€€</td>
<td>€€€</td>
<td>€€</td>
<td>€</td>
</tr>
</tbody>
</table>
Laminates for Pouches – Barrier Layers

**Barrier Layer**
- Can be a discrete layer or barrier can be incorporated into exterior or sealant layers

**Common Barrier Materials**
- Aluminum foil
- Metallised OPET or OPP
- Oxide Coated Films
# Laminates for Pouches – Barrier Layers

<table>
<thead>
<tr>
<th></th>
<th>Aluminum Foil</th>
<th>Metallised Film</th>
<th>Oxide Coated Film</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture Barrier</td>
<td>Best</td>
<td>Good</td>
<td>Better</td>
</tr>
<tr>
<td>Oxygen Barrier</td>
<td>Best</td>
<td>Good</td>
<td>Better</td>
</tr>
<tr>
<td>Light/UV Barrier</td>
<td>Best</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Clarity</td>
<td>Poor</td>
<td>Poor</td>
<td>Excellent</td>
</tr>
<tr>
<td>¹Mechanical Strength</td>
<td>Poor</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td>²Durability of Barrier</td>
<td>Excellent</td>
<td>Fair</td>
<td>Good</td>
</tr>
<tr>
<td>Lead times</td>
<td>Long</td>
<td>Short</td>
<td>Long</td>
</tr>
<tr>
<td>Relative Cost</td>
<td>€€</td>
<td>€</td>
<td>€€€</td>
</tr>
</tbody>
</table>

¹Mechanical strength of metallised film and oxide coated films depend on the properties of the base film (BOPET, BOPP, etc)

²Metallisation and oxide coatings can scratch off base material. Foil must be protected from flex cracking which can cause pinholes.
Role of the Sealant Layer

- Seal Initiation
- Hot Tack
- Caulk and Flow
- Peelable or Weld Seal
- Coefficient of Friction
- Clarity or Opacity
- Product Compatibility / Regulatory Approval
- Seal Transfer / Tamper Evidence
- Puncture Strength
- Barrier

Common Sealant Materials

- Polyethylene and PE Copolymers
  - LDPE, LLDPE, mLLDPE
  - EVA, EAA/EMAA, Ionomer
- Peelable Systems
### Laminates for Pouches – Sealant Layers

<table>
<thead>
<tr>
<th></th>
<th>Seal Initiation Temp</th>
<th>Hot Tack</th>
<th>Puncture Strength</th>
<th>Relative Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>mLLDPE</td>
<td>96 C</td>
<td>Excellent</td>
<td>Excellent</td>
<td>€€€</td>
</tr>
<tr>
<td>EAA/EMAA</td>
<td>113 C</td>
<td>Good</td>
<td>Good</td>
<td>€€€</td>
</tr>
<tr>
<td>Ionomer</td>
<td>93 C</td>
<td>Good</td>
<td>Good</td>
<td>€</td>
</tr>
<tr>
<td>EVA</td>
<td>96 C</td>
<td>Poor</td>
<td>Poor</td>
<td>€€€</td>
</tr>
<tr>
<td>LLDPE</td>
<td>129 C</td>
<td>Excellent</td>
<td>Good</td>
<td>€</td>
</tr>
<tr>
<td>LDPE</td>
<td>121 C</td>
<td>Fair</td>
<td>Fair</td>
<td>€€€</td>
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</tbody>
</table>

### Peelable Systems
- Blend of two or more immiscible polymers
- Can adjust peel force by adjusting blend ratio
- Creates cohesive split of peelable layer upon opening
- Provides white seal transfer / tamper evidence
HFFS Coextruded Film Rollstock

Flexible Forming Film Properties
- Ability to Thermoform
- Mechanical Properties
  - Puncture Strength
  - Abrasion Resistance
- Sterilisation Method Compatibility
- Ease of Cutting on FFS Equipment
- Clarity
- Ability to Heat Seal to Lidding Film

Common Forming Films
- EVA/Ionomer/EVA
- PA/PE Coextrusions
  - Cast/Blown films
  - ICE™
### HFFS Coextruded Film Rollstock

<table>
<thead>
<tr>
<th></th>
<th>EVA/Ionomer/ EVA</th>
<th>Cast PA/PE</th>
<th>Blown PA/PE</th>
<th>²PA ICE™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of Thermoforming</td>
<td>Excellent</td>
<td>Good</td>
<td>Fair</td>
<td>Good</td>
</tr>
<tr>
<td>Ease of Cutting</td>
<td>Excellent</td>
<td>Fair</td>
<td>Fair</td>
<td>Fair</td>
</tr>
<tr>
<td>Puncture Strength</td>
<td>Fair</td>
<td>Good</td>
<td>Good</td>
<td>Excellent</td>
</tr>
<tr>
<td>Abrasion Resistance</td>
<td>Fair</td>
<td>Good</td>
<td>Good</td>
<td>Excellent</td>
</tr>
<tr>
<td>Gamma Sterilisation</td>
<td>Very Stable</td>
<td>Some degradation</td>
<td>Some degradation</td>
<td>Some degradation</td>
</tr>
<tr>
<td>¹Relative Cost</td>
<td>€€€</td>
<td>€</td>
<td>€€</td>
<td>€€</td>
</tr>
</tbody>
</table>

¹Material costs of PA/PE is more expensive than EVA/Ionomer/EVA, but can downgauge film due to superior mechanical strength so actual cost is less

²ICE™ is Bemis’ proprietary quench technology that enhances mechanical strength and forming properties of 7-layer PA/PE coextruded film
HFFS Coextruded Film Rollstock

Technology advances offer improved performance and lower cost
Failure Modes & Testing – Films and Laminates
Gels

Package Integrity
- Gels will not fall out
- Will remain embedded through sealing and forming

Analysis / Detection
- Composition analysis by FTIR
- Microscopy
- Hot Stage Microscopy
- Cross Sections
- Vision Inspection
Pinholes in Foil

Package Integrity

- Not a through hole
- Effect on barrier negligible compared to ingress through seal cross section

Analysis

- Microscopy
Punctures

Package Integrity
- Through hole
- Sterile barrier is compromised

Analysis
- Microscopy
- Can usually determine if puncture occurred from outside in or inside out
Abrasions

Package Integrity
- Through hole
- Sterile barrier is compromised

Analysis
- Microscopy
- Can often determine if abrasion occurred from outside of package or inside
Flex Crack

Package Integrity

- Through hole
- Sterile barrier is compromised

Analysis

- Microscopy
Analytical Tools

**Stereoscope**
- For general ID of defect
- Also used for:
  - Film cross section
  - Gel analysis

**SEM**
- Surface topography analysis
- Up to 20,000x magnification

**FTIR**
- Identification of film layer or contaminants
Mechanical Testing

Slow Puncture (ASTM F-1306)  Gelbo Flex (ASTM F-392)
Thank You

Any Questions?