One-Side Clear Active Barrier Packaging for Moisture Sensitive Medical Devices:

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ABSTRACT

A new one-side clear, active, ultra high barrier peelable package is described for moisture sensitive medical devices that will provide revolutionary advantages over current peelable all foil constructions. While heavy foil laminates typically run on sheet fed equipment for these applications, the more competitive packaging needs to run on higher speed continuous roll fed equipment with fewer operation steps in manufacturing. The clear peelable high barrier lidding enhances productivity by allowing integration of roll fed processes and eliminates the complexity of matching the outer label print copy with product identification that may be included inside the packages. Breakthrough technology provides a transparent ultra high barrier film, together with an active moisture barrier to provide a 5+ year projected shelf life at real-time conditions, based on laboratory tests.

BACKGROUND

An ultimate goal of flexible packaging suppliers has been to provide "foil like" barrier packaging without the opacity and metal associated with foil packaging. Developments of vacuum applied metal or ceramic coatings on oriented films have had incremental contributions toward the ultimate goal of "foil-like" barrier performance, but never achieving equivalency for moisture sensitive products.

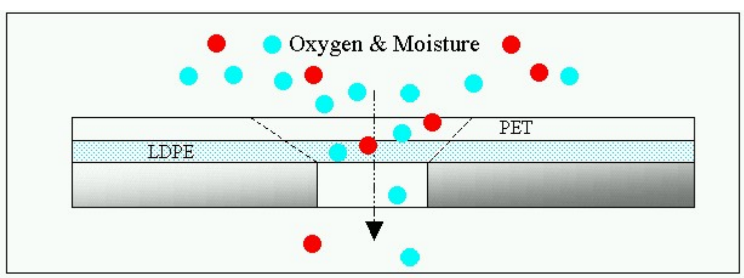
Active barriers have been developed for both oxygen and water vapor which offer advantages over substrates such as aluminum foil, glass or barrier film with vacuum deposition metal or ceramic, namely the ability to capture oxygen or moisture from the headspace of the package.

Medical products such as absorbable closures and drug coated devices must perform with a high degree of certainty. In order to insure this reliability, the packaging must be sufficiently robust as to guarantee no failures. For this reason heavy foils have often been used. Thin gauges of foil below 25µ in thickness are known to contain pinholes. In general, the thinner the foil, the more prevalent will be the numbers of pinholes[1]. The transmission of moisture through the pinholes is governed by the size of the pinhole and the materials adjacent to the pinhole which will govern the transmission rate according to Fick's law[2] (see Figure 1):

where: $1 / \text{Combined Transmission Rate} = \Sigma\,(\text{layer thickness (i)}/\ \text{layer transmission rate (i)})$

$\text{Combined Transmission Rate} = 1/\ \Sigma\,(\text{layer thickness (i)}/\ \text{layer transmission rate (i)})$

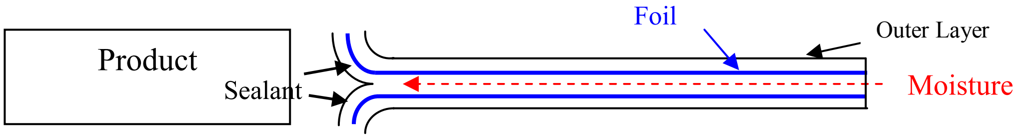
Figure 1
Transmission through pinholes in foil



Although these barrier polymers restrict the transmission of water vapor into a package, some moisture will slowly permeate into the package and eventually adversely affect the product. Even when continuous aluminum foil blocks the transmission of water through the package structure, the sealed edges of the package will provide a transmission path for water vapor into the package interior (see Figure 2) and eventually cause the moisture level inside the package to exceed the tolerance of a moisture sensitive product.

Figure 2

Edge Transmission into a Package



DISCUSSION:

A technologically advanced, proprietary, clear lidding that has oxygen and water vapor barrier significantly better than could have been achieved previously[3]. This results in transmission rates of <0.003 g/m^2 day for moisture and <0.005 cc/m^2 day for oxygen. The film is presently being commercially produced and sold into high barrier packaging applications.

Even though the transmission rate is very low and below the sensitivity of most commercial instruments to measure, it still represents 3,000 µg of moisture per square meter per day at 90% RH and 38°C. This value is still too high for extended shelf lives of some moisture sensitive products. What makes this film acceptable as part of a package system for such moisture sensitive products is the ability of the foil bottom web to scavenge the small amount of moisture which comes through the clear film during the life of the package. In the proposed structure this ultra barrier clear film is sealed to a foil back or bottom web lamination. This bottom web incorporates a moisture scavenging desiccant into the heat seal ply of the lamination. To accomplish this scavenging, a number of active components were tested[4].

Four classes of desiccants we evaluated included:

1. Physical types such as molecular sieves
2. Salts with waters of hydration types
3. Chemically reactive types, such as $CaO + H_2O \rightarrow Ca(OH)_2$
4. Super absorbent polymer (SAP) types, such as polyacrylic acid

The literature and our testing indicates that CaO will not release moisture back into the package headspace when the temperature increases, as in the case of summertime exposures in a closed vehicle or when the pressure decreases, as in the case of airline transportation. CaO also reacts more slowly than the physical and salt types, but achieves a low level of equilibrium humidity. While this means that recovery from moisture exposure is not rapid, it facilitates the use of the packaging film in unconditioned environments as long as it is protected during storage, thus aiding in the safe and effective conversion during the filling process.

Figure 3
Comparison of Desiccant Types

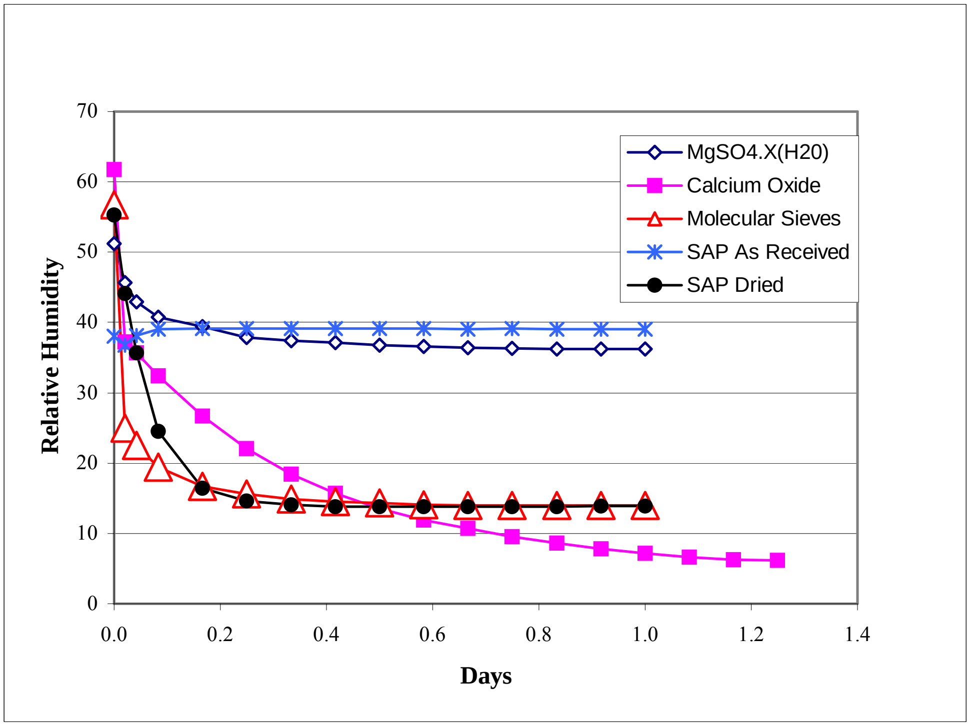
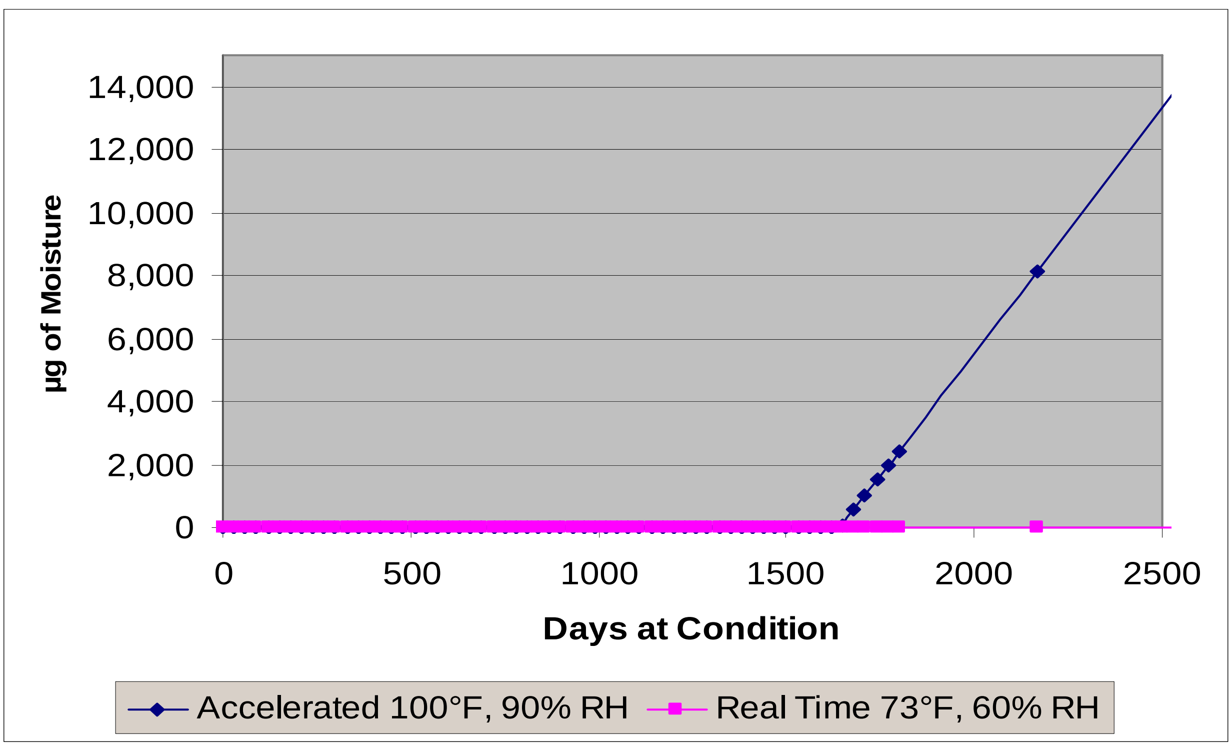


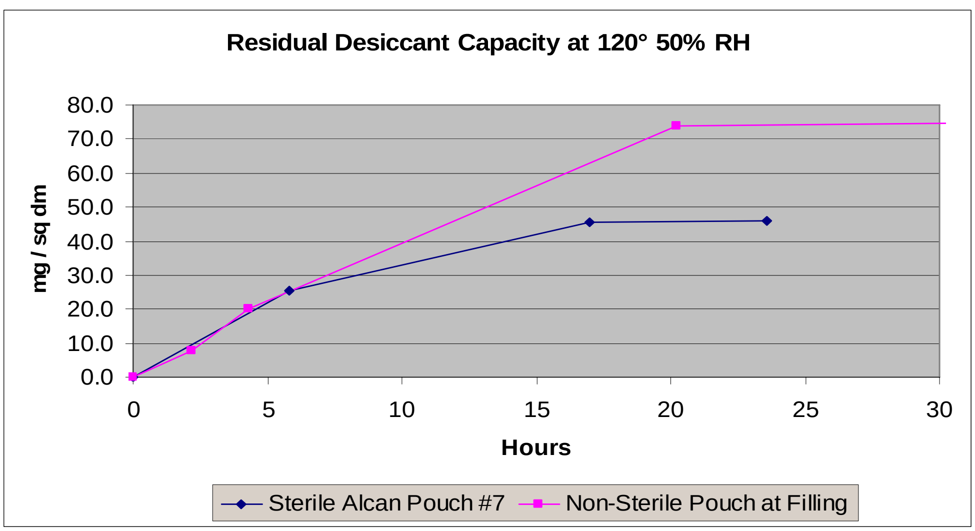
Figure 4
Theoretical Moisture Gain of Product in Gamma Sterilized Active Package



Based on extensive testing and field evaluations, the proposed package moisture would start permeating through the structure and be scavenged by the CaO desiccant on the inside where the humidity would be about 5% RH or lower. This would continue for a period of time based on the amount of CaO present and the area of the clear high barrier film. In the figure below the flat portion of the product moisture take-up represents the period when the scavenger is active. When this capacity is reached the humidity inside the package will increase. The shelf life is reached when the product reaches it's tolerance for moisture. A graphic display of a theoretical package in a hot and moist environment (100°F / 38°C & 90% RH) and a more typical (73°F / 23°C, 50% RH) environment is shown in Figure 4. In a more typical environment, the package contents will not see moisture gain for over 10+ years.

In the best case, a dry sterilization process would be used so that all of the desiccant in the back web sealant can be used to capture moisture that would come through the ultra high barrier clear front web or seals. The shelf life is extended primarily because of the moisture scavenging capacity of the back web's active component. The survival of the desiccant incorporated into the sealant of the foil back web during a high humidity sterilization process, such as ethylene oxide (EtO), is accomplished by two factors. First the reaction rate of water vapor with the CaO desiccant is much less than most desiccants. The second factor is the placement of a specialized moisture transmission moderating layer between the desiccant and the interior of the package, within a proprietary sealant coextrusion. This ensures that the intense but brief exposure to moisture during the EtO cycle leaves enough desiccant to provide protection through the life of the product.

Based on an actual customer trial in an all foil structure, we expect approximately 60% of the desiccant to survive the harshest EtO sterilization process (see the Sterile Alcan Pouch Curve) and be available to prevent moisture ingress for a significant period of time, thus achieving a 5 year shelf life requirement. Nearly 100% of the desiccant would remain active after dry sterilization processes such as electron beam or cobalt.



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[1] Murray, "The Impact of Foil Pinholes and Flex Cracks on the Moisture and Oxygen Barrier of Flexible Packaging" TAPPI, PLACE Conference, September 2005, Las Vegas, NV.
[2] Polymer Permeability, ed. J. Comyn, Elsevier Applier Science Publishers, 1985 edition. P. 291
[3] Reference to Double Ceramis Film
[4] Murray, Merical and Kaas "Moisture Scavenging Packaging for Diagnostic Test Strips, Pharmaceuticals and other Moisture Sensitive Products" TAPPI, PLACE Conference, August 2003, Orlando, FL.

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St Louis, MO

One-Side Clear Active Barrier Packaging

For Moisture Sensitive Medical Devices

Presented by:

Rick Johnson

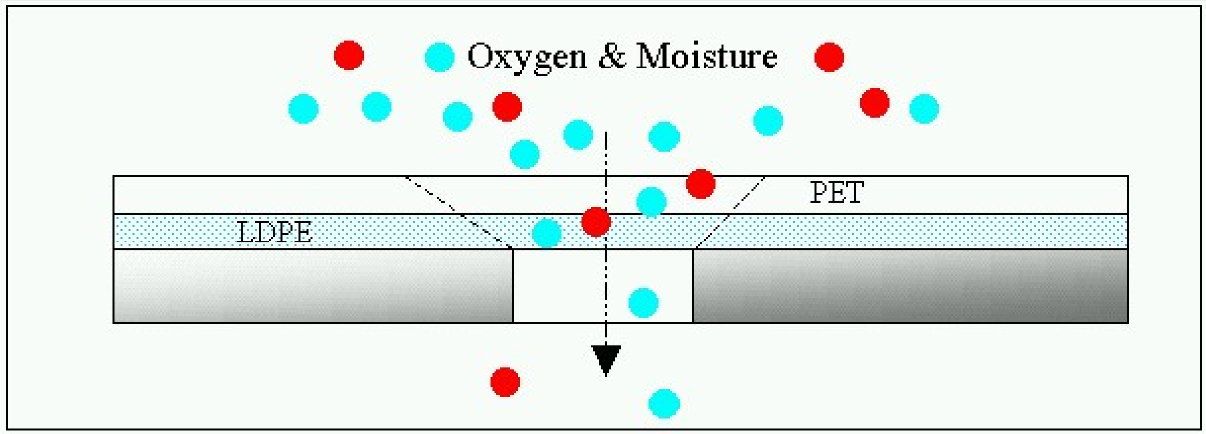
Research Fellow

Alcan Packaging

Current Technology

- Heavy foil laminates are typically used for packaging moisture sensitive medical devices.
- Without transparency, product identification is ordinarily used inside and outside of packages.
- Transparent ultra high barrier clear films are in commercial use using vacuum deposition and inorganic coatings.
- Active moisture barrier packaging was developed using CaO and other desiccants.

Transmission Through Pinholes

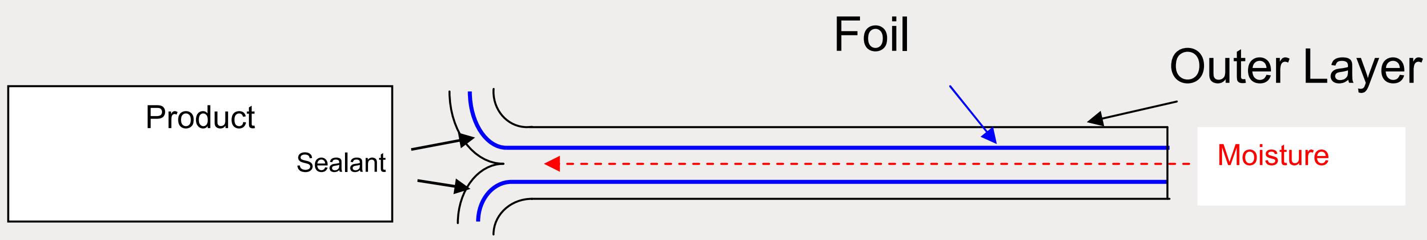


The transmission of oxygen and moisture through foil pinholes is governed by the size of the pinhole and the materials adjacent to it, according to Fick's Law where:

Combined Transmission Rate =

1/ Σ (layer thickness (i)/ layer transmission rate (i))

Edge Transmission



Even when continuous aluminum foil blocks transmission through the package structure, the sealed edges will provide a transmission path for water vapor into the package interior and eventually cause the moisture level inside the package to exceed the tolerance of a moisture sensitive product.

Reasons for Desiccants Included in Packaging

- Product sensitivity to moisture
- Foil pinholes in thinner gauge foils
- Transmission through exposed cut edges
- Transmission through non-foil webs
- Desiccant sachets are expensive, time consuming to insert and can contaminate the product

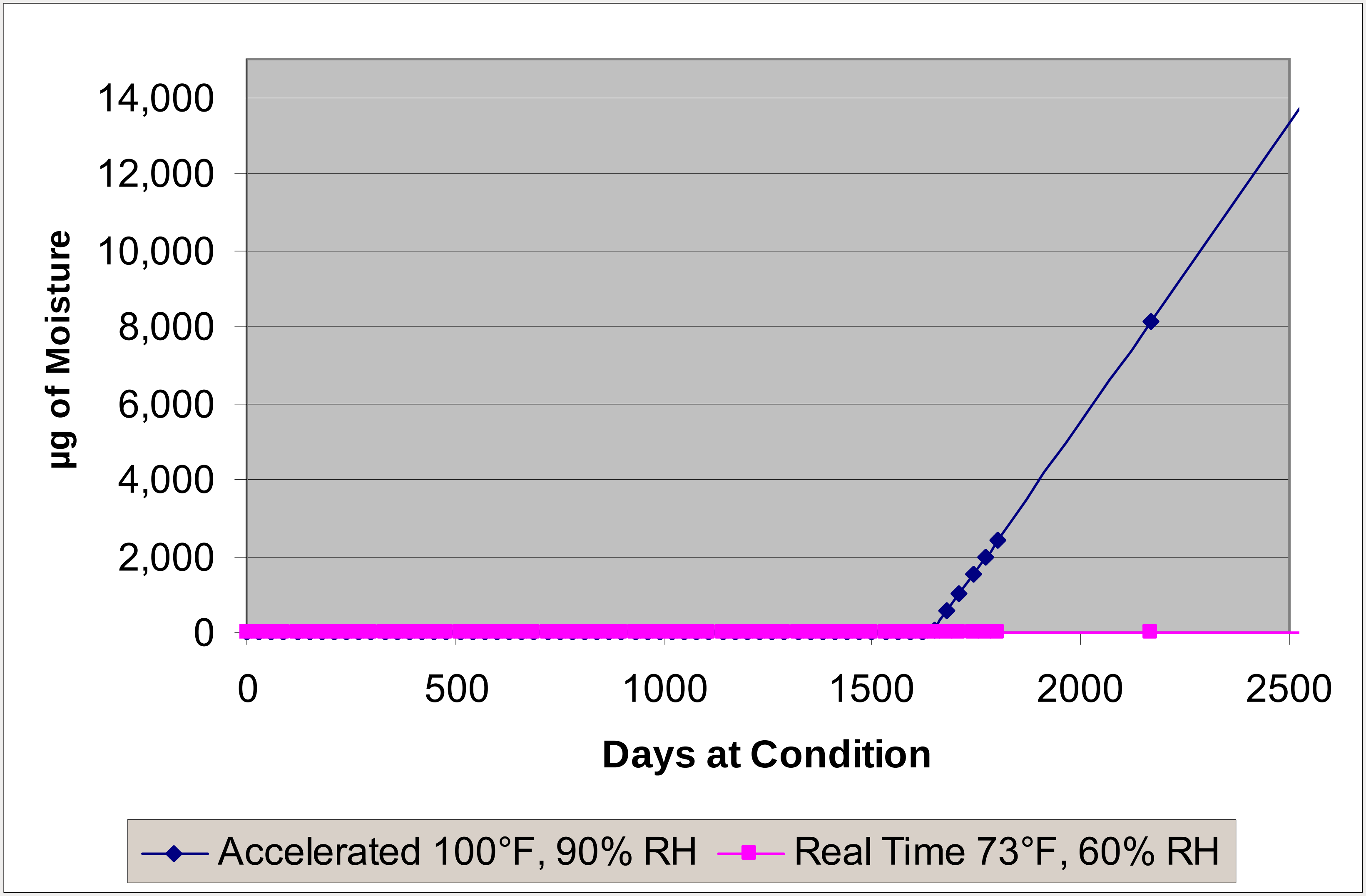
Chemical Desiccants Are Ideal

- Physical types, such as molecular sieves (too fast & need to be regenerated when package is made)
- Salts with waters of hydration types (variable performance)
- Super absorbent polymer (SAP) types, such as polyacrylic acid used in diapers (will not reduce humidity to acceptable levels)
- Chemically reactive types, such as $CaO + H_2O \rightarrow Ca(OH)_2$ (cannot release moisture back into the package)

Performance Model

- Compute the amount of moisture coming into the package from:
  - Clear ultra-high barrier films (WVTR = 0.003 g/m^2 day)
  - Pinholes in the foil, based on current foil specifications and laminate structure
  - Transmission through exposed sealed edges
- Compute package life based on desiccant capacity, exposure conditions and product sensitivity.

Days of Storage vs. Moisture Exposure to Product



EtO Sterilization

- Because CaO is slower reacting than typical desiccants, brief exposures to moisture can be tolerated during filling operations and during the sterilization cycle.

- Use of a protective layer over the desiccant layer within a proprietary sealant coextrusion can guarantee survival of enough desiccant to insure an extended shelf life.

Conclusion

- By combining active packaging with clear ultra-high barrier peelable laminates for moisture sensitive medical devices, a 5+ year shelf life can be achieved.

- Using a two-side foil package or closing off a breather strip after EtO sterilization an extended shelf life can be ensured for certain medical devices which degrade in the presence of moisture.

Acknowledgements

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  - Rick Merical, Director of R&D
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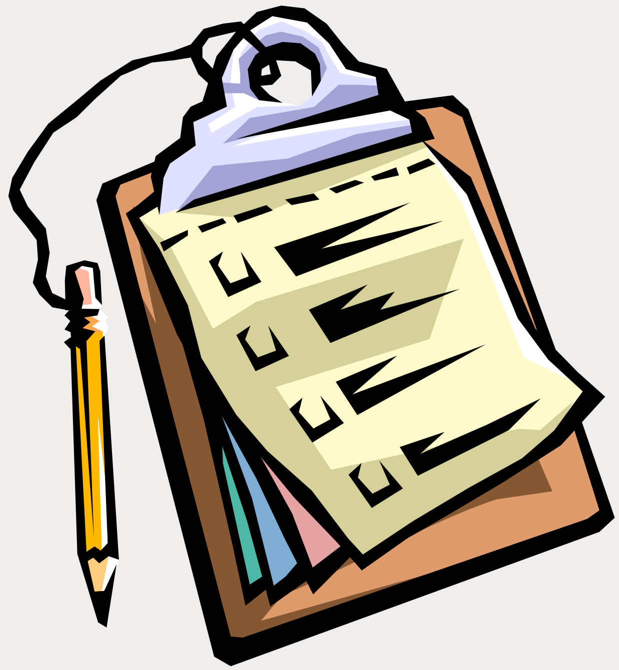
- TAPPI PLACE Active and Barrier Packaging committee for sponsoring the talk.

Thank You

PRESENTED BY

Rick Johnson

Research Fellow



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