

## Barrier Structure Material Options Made Crystal Clear

The use of a clear barrier packaging may often be the first choice of a device manufacturer for their product, but performance concerns may cause them to reconsider that option. However, significant advances in the materials have enabled medical device makers to take advantage of this ideal alternative to more traditional, non-transparent packaging. This article reviews the various materials and provides benefits of each.

By Dhuanne Dodrill

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Material	Flat O <sub>2</sub> TR (cc/m <sup>2</sup> - day)	Flat O <sub>2</sub> TR (cc/100in <sup>2</sup> -day)	Flexed O <sub>2</sub> TR (cc/m <sup>2</sup> - day)	Flexed O <sub>2</sub> TR (cc/100in <sup>2</sup> -day)
48 ga oPET / 35 ga Foil / 2 mil LLDPE	0.47	0.03	50	3.2
48 ga oPET / Met / 2 mil LLDPE	1.6	0.1	11	0.7
48 ga oPET/ ClearFoil®A / 2 mil LLDPE	0.62	0.04	7.8	0.5
48 ga oPET/ ClearFoil®F / 2 mil LLDPE	<0.047	<0.003	<0.047	<0.003

**Table 1:** Barrier properties after flexing

Medical devices continue to become increasingly complex and sophisticated—the advent of combination drug/device products certainly illustrates this. The demands that we place on the packaging of medical products have also evolved. In addition to maintaining a sterile barrier and allowing for aseptic presentation of the product, packaging is expected to extend shelf life, ensure product efficacy, and

promote patient safety.

Clear barrier packaging materials play an increasingly important role when designing packaging solutions for sensitive materials. Product visibility allows for packaged product inspection via vision systems and metal detectors as well as manual visual inspection by both the manufacturer and the end user. Because any printing on the device or on labels inside the package can be seen, the labeling process can be simplified, reducing the risk of labeling mix-ups and further promoting patient safety. With the advances that have been made in clear barrier materials, this can be achieved without compromising the barrier properties. In fact, barrier levels that are comparable or even exceed those of thin-gauge aluminum foils can be achieved with today's clear materials.

Clear high-barrier materials are available in two forms: barrier films and barrier coatings. For more complex applications, combinations of films and coatings may be required. In order to understand the barrier that will be provided by the finished package, it is important to factor in not only the permeation through the face of the material

but also the ingress through the seal. The sealants used in packaging materials often provide little barrier to gasses. As a result, ingress through the seal can result in a significant barrier loss. Ingress through the seal can be theoretically calculated or determined through whole package barrier testing.

## EVOH

Ethylene vinyl alcohol (EVOH) is one of the most common clear high barrier films used today. It is applied as a discrete layer in a coextrusion. EVOH provides excellent oxygen barrier, in the range of 0.006 – 0.12 cc-mil/100 in<sup>2</sup>-day. The barrier that a particular EVOH film provides is dependent upon a number of factors:

- Mole Percent—As the ethylene mole percent increases, the barrier decreases.

- Degree of Crystallinity—As the degree of crystallinity increases, the barrier properties improve.

- Thickness—As with all films, as the thickness increases, the barrier increases.

- Temperature—As the temperature increases, the barrier decreases.

- Humidity—At high humidity levels, the barrier provided by EVOH drops rapidly. Note: it is the humidity level at the EVOH interface rather than ambient humidity that is critical.

In addition to providing excellent oxygen barrier, EVOH is also an excellent odor and aroma barrier. It has the added advantage of being thermoformable, making it popular for three-dimensional applications. EVOH has a long history and is well understood.

## Polyacrylonitrile

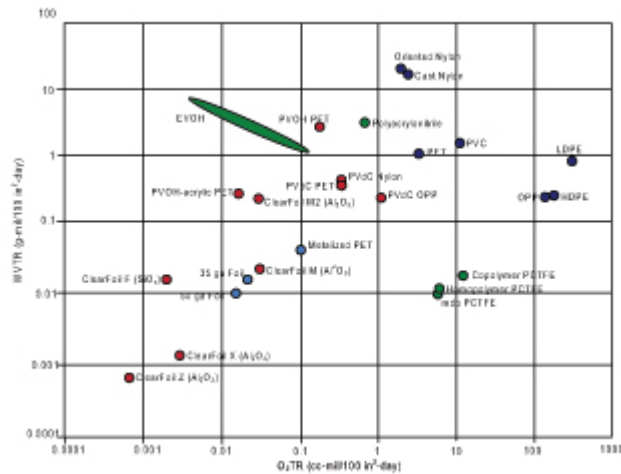
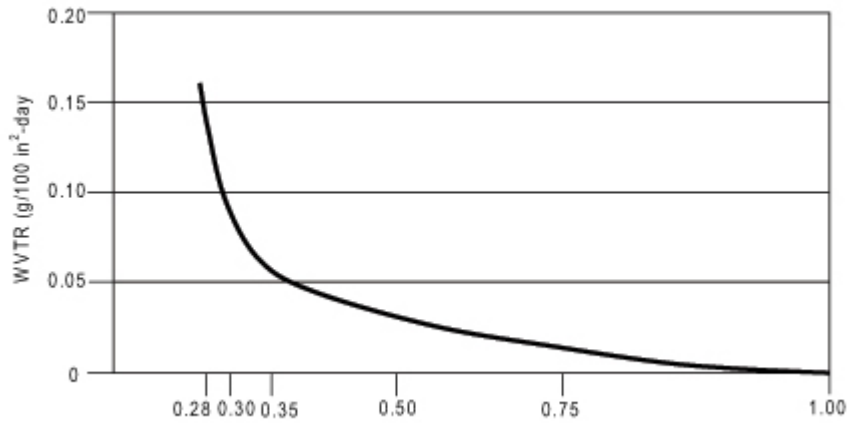


Figure 1: Relative barrier properties



**Figure 2:** Water vapor transmission rate of thin-gage foil

Polyacrylonitrile (Barex) is film that offers a good oxygen barrier, in the neighborhood of 0.7 cc-mil/100in<sup>2</sup>-day. What makes polyacrylonitrile unique is that it can also be used as a sealant. Because Barex can also be thermoformed, it is a very versatile product. It is ideal for very sensitive applications where oxygen ingress through the seal is a concern.

### PCTFE

Polychlorotrifluoroethylene (PCTFE or Aclar) film provides excellent moisture barrier. It is available as a copolymer or a homopolymer with water vapor transmission rates of approximately 0.038 g-mil/100in<sup>2</sup>-day and 0.016 g-mil/100in<sup>2</sup>-day respectively. PCTFE is commonly used in blister (thermoformed) packages where moisture barrier is required. It is inert, chemically resistant, has excellent clarity, and, unlike many barrier materials, it is flex-crack resistant.

### PVdC

Polyvinylidene chloride (PVdC) is a widely used barrier material with a long history. While PVdC is available as an oriented film and a discrete layer in coextruded films, it is more commonly used as a barrier coating. PVdC has good oxygen and moisture barrier properties and provides an excellent aroma and flavor barrier.

The barrier level of PVdC coatings are dependent upon the coating thickness. Much lower transmission rates can be achieved by applying significantly more coating as is common in the pharmaceutical industry.

Because PVdC contains chlorine, hydrochloric acid can be generated under certain conditions. As a result, specialized equipment must be used to apply the coating and the proper equipment must be used if the packaging material is to be incinerated.



**ClearFoil** (aluminum-oxide coated) high barrier packages

### PVOH



**ClearFoil** header pouch with peel-open

feature

Polyvinyl alcohol (PVOH) is also available as a film or a coating. As a coating, PVOH provides excellent oxygen barrier. The barrier of a PVOH coating is dependent upon the coating thickness. PVOH is moisture sensitive and will dissolve when exposed to water or high humidity.

### Silicon/Aluminum Oxide

Silicon Oxide ( $\text{SiO}_x$ ) coatings are generally applied as a vacuum deposition onto films such as polyester and nylon.  $\text{SiO}_x$  coatings provide excellent oxygen and water vapor barrier properties in a variety of ranges.

A concern is often expressed regarding the ability of silicon oxide coatings to maintain their barrier when flexed. The reality is that most grades perform favorably when compared to aluminum foil and metallized composites. For more demanding applications, there are grades available that provide tremendous flex-crack resistance. The table details the transmission rates of a variety of substrates after flexing.

Aluminum oxide ( $\text{Al}_2\text{O}_3$ ) coated substrates provide similar properties and are used for the same applications as silicon oxide coated substrates. Unlike the slight amber tint seen in  $\text{SiO}_x$  coated films, these films are clear. However, they may have a slightly gray cast when many layers are stacked.

$\text{SiO}_x$  and  $\text{Al}_2\text{O}_3$  coatings are available in grades appropriate for retort/autoclave applications.

The conventional wisdom is that composite packaging materials that use  $\text{SiO}_x$  or  $\text{Al}_2\text{O}_3$  coatings as the barrier will be more expensive than aluminum foil composites. This conclusion is often reached after comparing the cost of the base aluminum foil (unlaminated) to the base  $\text{SiO}_x$  or  $\text{Al}_2\text{O}_3$  coated product. However, it ignores the fact that aluminum foil must be protected on both sides whereas the  $\text{SiO}_x$  or  $\text{Al}_2\text{O}_3$  coated product may only need a sealant. The cost of the additional layer and processing necessary for aluminum foil often results in a composite structure that is more expensive than a comparable  $\text{SiO}_x$  or  $\text{Al}_2\text{O}_3$  composite.



**High barrier** ClearFoil header pouch provides for product visibility

### Conclusion

Figure 1 displays the relative barrier properties of barrier materials discussed here as they compare to "standard" packaging materials, thin gauge aluminum foils, and metallized films. This chart clearly shows that clear barrier materials can outperform metallized films and even thin gauge foil.

While the assumption is often that aluminum foil provides a total barrier, pinholes that are inherently present in thin gauge aluminum foil will impact barrier. As the thickness of aluminum foil decreases, the level of pinholes dramatically increases. Figure 2 illustrates the affect of pinholes on water vapor transmission rate as detailed in ASTM B479 Standard Specification for Annealed Aluminum and Aluminum-Alloy Foil for Flexible Barrier, Food Contact, and Other Applications.

There is no one ideal barrier material for all products. Achieving the correct balance of barrier, performance, and economics is very much application dependent. Considerations include:

- Type of barrier needed for the application (oxygen, water vapor, aroma, chemical, ultra-violet light, and/or microbial barriers are common needs)
- The product itself and its compatibility with the packaging materials (for example, many options can be ruled out if the product contains water, is chemically active, or is sharp.)
- The equipment that will be used to process the packaging material
- The sterilization method (if applicable)
- Specific environmental and/or disposal requirements
- The cost of the packaging system

With the advances in  $\text{SiO}_x$  and  $\text{Al}_2\text{O}_3$  coated products, clear barrier options exist that can provide barrier properties comparable to or even better than aluminum foil and often at a lower price. Today, even the most demanding products can be packaged in clear materials.

#### Online

For additional information on the technologies and products discussed in this article, see *MDT* online at [www.mdtmag.com](http://www.mdtmag.com) or Rollprint Packaging Products Inc. at [www.rollprint.com](http://www.rollprint.com)

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