



Blister News: COC Resin, Foil, and Lidding Innovations

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Right now, COCs are more widely known in Europe and Japan, but a number of suppliers are developing COC products for the US market.

For the first time in at least a decade, pharmaceutical manufacturers have a new option for blister packaging. Joining traditional blister materials such as foil, polyvinyl chloride (PVC), and fluoropolymer film are films based on a relatively new group of resins, cyclic olefin copolymers (COCs), that show potential for use in syringe bodies and other containers and packaging components.

Part of the olefin family, which includes polyethylene (PE) and polypropylene (PP), COCs offer excellent clarity, high stiffness, high tensile modulus, low elongation at break, good surface hardness and thermoformability, and compatibility with standard thermoforming tooling and traditional backings or liddings. COCs include other important characteristics such as a very high water vapor barrier (about 10 times that of PVC and more than double that of polyvinylidene chloride [PVDC]-coated PVC), low extractables, excellent biocompatibility, high light transmission (even in the near-UV range), dimensional stability, and compliance with USP Class VI and applicable FDA regulations (see Table I). The material also is easily metalized for appearance or enhanced barrier properties and compatible with radiation and ethylene oxide sterilization processes. COCs offer good chemical resistance but are not compatible with aliphatic and aromatic hydrocarbons and certain fats and oils. Lower density (1.02 g/cm³ versus 1.4 g/cm³ for PVC) means higher yield per pound and potential cost savings because less material is needed.

Although COCs are more widely known in Europe and Japan, a number of suppliers have introduced or are developing COC products for the US market. COC resin relies on Ziegler-Natta or metallocene catalysts to link cyclic and linear olefins and is produced in

commercial quantities by Ticona GmbH's new 30,000-ton/year plant, which started producing it in September 2000 in Oberhausen, Germany (Topas COC, Frankfurt, Germany). Developmental quantities of resin are available from at least one other company, Mitsui Chemical (Tokyo, Japan).

At the Ticona plant, metallocene catalysts enable copolymerization of ethylene and norbornene, an olefin with a rigid bridged-ring structure. This is accomplished by reacting ethylene and cyclopentadiene to form 2-norbornene. This bicyclic olefin is then reacted with ethylene to create COC. The COC is totally amorphous because the norbornene is randomly incorporated into the main molecular chain. More norbornene causes the resin to become stiffer and stronger and its glass transition temperature (the temperature at which the plastic softens and molecular chains become more mobile) to rise.

COCs, sometimes blended with PE, can be extruded into a film or sheet or coextruded into a multilayer structure. For push-through blister packages, COC-based structures are generally three-layer laminates (A-B-A) or five-layer coextrusions (A-tie layer-B-tie layer-A), with tie layers providing good bonding between layers. The resulting laminates and coextrusions handle like PVC or PVDC-coated PVC and run on existing thermoform-fill-seal equipment with little, if any, modification. COC-based materials offer a wide processing window and relatively low forming temperatures (100–130 °C), thereby decreasing energy consumption and reducing cycle times as much as 20%. The material draws uniformly

Table I: COC properties.

Density (g/cm ³)	1.02
Permeability to water vapor (23 °C, 85% RH, g mL/100 in ² /24 h atm)	0.071
Luminous transmittance (%)	92
Glass transition temperature (°C)	85
Thermoforming temperature (°C)	110–130
Tensile modulus (psi)	377,000

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Holographic blister backing material is in development to further the pharmaceutical manufacturer's anticounterfeiting crusade.

so corners thin less and wall thickness is more consistent, enhancing the material's water vapor barrier properties.

Inner and outer layers of multilayer blister film generally consist of PP, PVC, PVDC-coated PVC, or PE. Depending on the resin chosen, the outer layers can boost impact strength and flexibility, impart grease resistance, or enhance sealability. PP layers, for example, enhance the film's flexibility and grease resistance but are not thick enough to affect clarity or formability.

All olefin structures like PP-COC-PP are of particular interest to companies seeking to eliminate halogen-based materials such as PVC and PVDC, which some view as less environmentally friendly. Because no chlorine or fluorine is present, halogen-free materials do not corrode equipment or form toxic hydrofluoric or hydrochloric acids when incinerated for disposal.

Bayer AG (Leverkusen, Germany), a pioneering user of COC resin, began using Topas COC grade 8007 to protect its aspirin tablets in the high-humidity environment of the tropics. Other Topas COC

grades could have been selected, but 8007 is the most ductile and the easiest to thermoform. It also offers superior barrier properties. The COC structure provides the aspirin tablets with a two-year shelf life and has been running on blister packaging equipment at a plant in Indonesia since 1999. The 360- μm PP-COC-PP laminate provides water vapor permeability of $<0.1 \text{ g}/(\text{m}^2/\text{day})$ at less cost than alternative materials offering equivalent barrier properties.

At least four companies are commercializing PP-COC-PP blister films (Amparis, Lawson Mardon Pharmcenter, Shelbyville, KY; Pharma-Films, VAW, Traverse City, MI; Integra Pharm C, Rexam Medical Packaging, Mundelein, IL; and Pentapharm COC films, Klöckner Pentaplast of America, Inc., Gordonsville, VA). PVC-COC-PVC laminates also are available as well as a PVDC-coated COC for applications that need a higher oxygen and water vapor barrier (Pentapharm COC films, Klöckner Pentaplast).

As yet, there are no commercial applications in the United States for the COC films. However, the first domestic application for COC blister films likely will be a new pharmaceutical product because existing products that have packaging changes are required to undergo stability testing again.

Foil innovations

With last year's consolidation in the aluminum industry and growing interest in high-barrier blister packaging, pharmaceutical manufacturers have a number of new foil choices. The first is a domestically produced coldform blister foil. Uni-Form 102 (Alcoa Flexible Packaging, Richmond, VA, formerly Reynolds Metals Co.) not only offers the usual advantages of foil —

100% barrier to oxygen, water vapor, and light — but also provides excellent machinability and deep-draw characteristics. Domestic production means short lead times for stock three- and four-ply structures.

Difficult-to-duplicate holographic blister backing material is in development to add another



tool to the pharmaceutical manufacturer's anticounterfeiting arsenal. Alcoa's plans to open a pharmaceutical center in Downingtown, PA this summer also are underway.

A domestic stocking program makes a two-week turnaround possible for other cold-formable foils (OptiForm aluminum-aluminum blister, Hueck Foils, LLC, Wall, NJ). Capable of a 10-mm draw, these cold-formable foils offer a choice of sealing layers, including PVC, low-density PE, ionomer, and PP as well as various heat-seal coatings. Later this year, the company will add coating and laminating capacity to its plant in South Carolina where printing and slitting already take place.

Lidding innovations

New offerings in blister package lidstock, or what sometimes is referred to as the backing or nonforming web, also are available. Most of these structures impart child resistance (CR) and must also offer senior-friendly manipulation under current Consumer Product Safety Commission requirements for special poison-prevention packaging. One example is a nonvinyl peel-push structure (Safety-Pak 285, Alcoa Flexible Packaging, Richmond, VA). The nonvinyl heat-seal coating requires less heat, thereby producing a package with crisper, easier-to-break perforations. Another new lidstock possibility, an untearable paper-film-foil structure, ensures packages will not fail CR-protocol testing (NoTear Safety-Pak 288, Alcoa). For situations where nonfoil structures are preferred, a peelable metallized film provides barrier properties (NonFoil Safety-Pak 282, Alcoa). **PT**

