

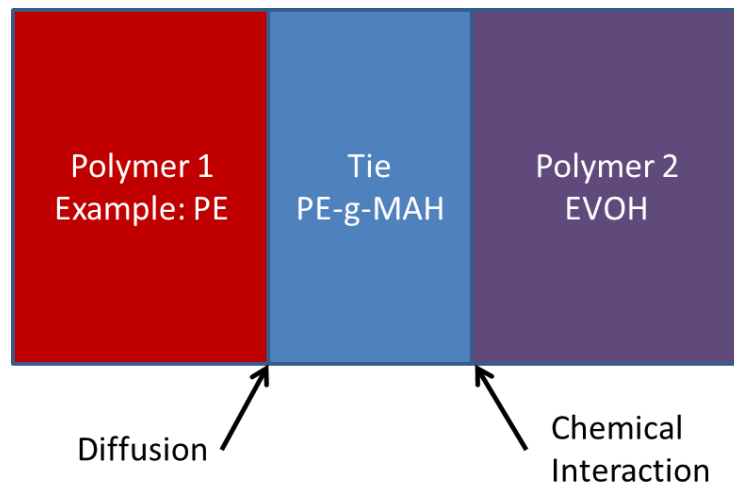
TIE LAYER TECHNOLOGY FOR MULTILAYER COEXTRUSION OF SINGLE-USE BIOPHARMA BAGS

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The needs of the demanding biopharma processing bag, such as barrier, toughness and heat sealability, cannot be met by any one polymer. As a result, multiple layers of different polymers, each playing its role in meeting the design requirements, are combined in coextrusion or lamination. Most of the polymers used in these layers do not naturally adhere to each other in the film making or lamination process without tie layers. Tie layers are polymer resins designed to provide adhesion between specific polymers in a given film manufacturing process.

In coextrusion, the polymer layers are brought together in the melt state. Tie resins are sandwiched between layers that do not bond on their own. Tie resins are typically comprised of a matrix resin and one or more functional components. The matrix resin is chosen to be compatible with one side to promote intermolecular diffusion at that interface. A reactive component is often added to bond to the other side, as illustrated in Figure 1. The reactive functionality may be incorporated into the tie resin by copolymerization, grafting or polymer alloying techniques. Other functional additives may also be present, such as tougheners, antioxidants and processing aids. There is a wide range of matrix resins, reactive components and functional agents used in the tie resin marketplace. Factors that should be considered when choosing a tie resin for the biopharma industry include the process used to make the film, the appropriate thickness and location of the tie and barrier layers to minimize extractables, the chemistry involved in the reactive and other functional ingredients, the additives used in the manufacture of the tie resin, and how downstream processes like sterilization will affect the tie layer and the adhesion at the interface. Without robust adhesion that stands up to abuse over time, the film could delaminate and compromise the single-use bag's integrity.



*Figure 1 – The concept of tie layers with an example of bonding polyethylene (PE) to ethylene vinyl alcohol (EVOH). Tie resins for this example often employ maleic anhydride (MAH) grafted PE, where the PE diffuses into the PE layer and the MAH chemically reacts with the hydroxyl groups on the EVOH. Reproduced with permission from Morris, B. A., 2016, *The Science and Technology of Flexible Packaging*, Elsevier.*