Technical Brief

POLY(ETHYLENE-CO-VINYL ACETATE)

INTRODUCTION

Common Applications

Poly(ethylene-co-vinyl acetate) or pEVA is a polymer commonly found in everyday products due to the wide range of properties that can be achieved by varying the vinyl acetate (VA) content and the molecular weight of the copolymer. pEVA is used in bulk form as a flexible plastic, and can also be foamed, compounded with other materials, and used as an emulsion. Example applications include hot melt adhesives, soccer cleats, paint, and plastic wrap. Foamed EVA is used for craft supplies, athletic shoe sole shock absorbents, and in a variety of other sports equipment as both structural components and cushioning material. It also serves as an encapsulating material for electronics and solar cells.

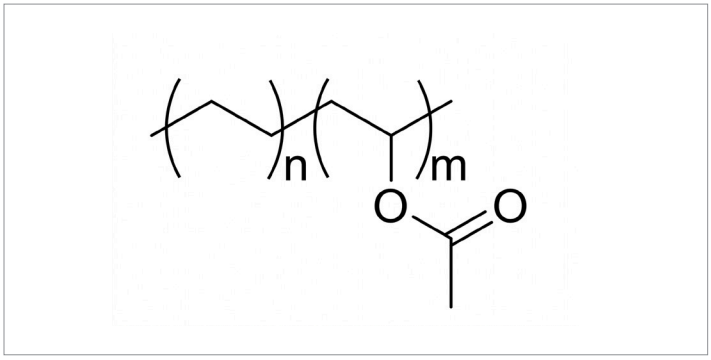

Figure 1: Chemical structure of pEVA

Biomedical Applications

As an important biocompatible (USP Class VI) material, pEVA is used as both a structural component and drug delivery vehicle in biomedical applications. Under physiological conditions, drugs will migrate through the pEVA over time and be released into the body to provide a steady supply of the required therapeutic. Because pEVA can be dissolved in solvents or blended with drug and melt extruded, a wide range of physical forms can be created including microparticles and essentially any shape that can be extruded or molded. Common biomedical applications for pEVA include microparticles, vaginal rings, and implanted devices that release drug over time as well as the structural and cushioning components of orthotics.

In addition to its direct uses, pEVA can also be hydrolyzed to provide a family of ethylene vinyl alcohol (pEVOH) copolymers with a similar range of properties and applications depending on the molecular weight and vinyl alcohol content of the material. This pEVOH can also be prepared under cGMP conditions for use in implantable devices, drug delivery applications, or embolic agents.

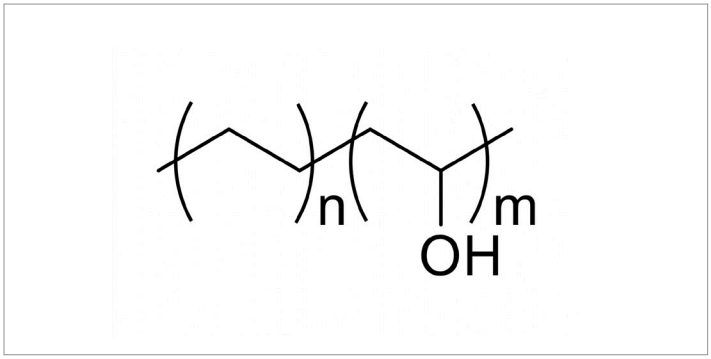

Figure 2: Chemical structure of pEVOH

MANUFACTURING

Poly(ethylene-co-vinyl acetate) is a random copolymer, mainly produced by radical chain polymerization between vinyl acetate and ethylene gas at high pressure (up to 30,000 psi). A wide variety of grades of pEVA available with different vinyl acetate contents and molecular weights can be produced using both large-scale industrial processes and moderate-scale processes more suited to specialized grades.

Industrial Manufacturing

Large-scale industrial EVA manufacturing processes that produce commonly used pEVA grades (9-28% VA content) are typically carried out using processes that require high pressure (around 15,000-30,000 psi) and temperatures greater than 100 °C. This bulk polymerization is the most common industrial process, where vinyl acetate has two roles, as a monomer and as the reaction solvent, and the unreacted VA monomer is then recovered and cycled back to the process. This process usually employs a continuous flow reactor in which vinyl acetate, initiator, and ethylene are fed at multiple locations along the reacting stream under high pressure to keep the polymerization rate at the desired steady-state conditions. Because this process requires complex and expensive manufacturing infrastructure and controls, it is typically used for high volume production (100s of kilotons/yr) and is not well suited for small-to-moderate scale production. The large volumes involved limit the number of EVA grades that are made available through this process. The continuous industrial process is also less conducive to cGMP manufacturing and the required documentation. Moreover, additives included in the industrial grades to minimize decomposition under the manufacturing conditions may not be suitable for use in medical grade materials.

cGMP Manufacturing
To provide specialized grades of pEVA made following cGMP guidelines, Polysciences has adopted a solution polymerization technique that allows using lower pressures, lower reaction temperatures, and equipment more suitable to lower volume production. The conditions of the polymerization allows for additive-free processing and EP/USP approved additives can be incorporated into the pEVA post-reaction if desired for particular applications.

Solution phase synthesis, typically carried out at 1,000 – 4,000 psi, can also be used to produce pEVA with a wide range of VA (vinyl acetate) contents and MFIs (melt flow index). In this process, the use of solvent allows for high ethylene saturation levels required to establish the ethylene/vinyl acetate molar ratio necessary at the lower pressure. Since lower pressures are used, less infrastructure is required making this process better suited to produce specialized pEVA grades at lower production volumes. This manufacturing technique also allows for batch processing, which is more conducive to a cGMP manufacturing environment.

Polysciences has employed this solution polymerization process to prepare pEVA grades with 9 – 80 wt% VA content at relatively lower pressures, and has developed reaction conditions that minimize chain transfer reactions to deliver an MFI range from 3 – 100+ across the spectrum of VA contents.

Biomedical pEVA by Polysciences
Because biomedical applications require specialized grades, approved additives, documented processes and characterization to meet specific release profiles and regulatory requirements, they are often not well served by large scale industrial manufacturers.

Polysciences manufactures pEVA with those specific requirements in mind, offering multiple grades that meet the demands of biomedical device manufacturers and pharmaceutical companies. These grades are prepared with the appropriate cGMP documentation and traceability, the option of including no additives or customized additive packages, and full characterization employing state-of-the-art analytical techniques.

As listed in Table 1, pEVA can be supplied with a wide range of VA contents and MFI values to meet the needs of both drug delivery and medical device manufacturing.

Polysciences pEVA Manufacturing Capabilities
Polysciences' batch processing capabilities yield pEVA lot sizes ranging from 1kg – 100kg. Our processes allow the preparation of pEVA with tailored properties to meet the needs of your specific applications. In addition to VA content, we're able to customize the MFI, particle size, pellet size and additive package. Specifically, pEVA may be supplied in its pristine additive-free form, or with any desired combination of antioxidants and slip aids incorporated into the polymer. The pEVA particle size distribution can be tailored using our liquid-nitrogen-cooled hammer mill. This cryomilling step is performed in a Class 100,000 (ISO 8) cleanroom using validated equipment, processes, and test methods.

We are pleased to offer our scientific and technical expertise, strong ISO 13485:2016 Quality Management System and cGMP capabilities to our partners in the pharmaceutical and medical device industries. Please reach out to us to find out how we can put our decades of knowledge and real-world experience to work for you.

Table 1. Grades of pEVA Polysciences has prepared on production scale

VA content %*	MFI**
Range available: 8 – 80%	Range available: 2 – 100+
9	2 - 3
9	7 - 12
15	6 - 10
28	2 - 10
28	26 - 30
33	30 - 60
40	30 - 60
77	100+

*Wt% of vinyl acetate monomer in the ethylene - vinyl acetate random copolymer

**Melt Flow Index (MFI) is a measure of how many grams of a polymer flow through a die in ten minutes and is an indirect determination of molecular weight (Mw). Generally, the lower the MFI value, the higher the polymer Mw.

Visit **Polysciences.com** anytime to place an order or inquire about custom formulations.

