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News Release

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EMD Millipore Introduces PureFlex™ Plus Single-Use Process Container Film for High-Volume Biopharmaceutical Applications

- **Rugged outer layer increases film's resistance to leak formation**
- **Ideal for applications where additional film robustness is needed to ensure container integrity**
- **Suitable for use throughout the entire manufacturing process**

Darmstadt, Germany, October 21, 2014 — [EMD Millipore](#), the life science division of [Merck KGaA](#) of Darmstadt, Germany, has expanded its single-use film offerings with the introduction of PureFlex™ Plus film, a robust, durable film used in the construction of Mobius® single-use process containers for biopharmaceutical manufacturing. The film's rugged outer layer offers strong resistance to leak formation, making it ideal for the demanding applications often encountered in large volume operations.

The PureFlex™ Plus film builds upon EMD Millipore's established PureFlex™ film technology, which was introduced in 2006 and has since been used by customers throughout the drug manufacturing process. PureFlex™ Plus film adds a new, more robust linear low density polyethylene (LLDPE) outer layer, which reduces susceptibility to leaks through abrasion, puncture, stretching and tearing. The inner layers of PureFlex™ Plus film are identical to the original PureFlex™ film product and offer the same well-characterized extractables profile and gas barrier properties. Because the fluid contact layer is the same in both films, current users of PureFlex™ film can incorporate PureFlex™ Plus



technology with reduced validation requirements. Original PureFlex™ film will remain available, however, for customers uninterested in a film change.

“Biopharmaceutical manufacturers are increasingly incorporating single-use components into their processes to maximize efficiency and reduce costs,” said Andrew Bulpin, Executive Vice President of EMD Millipore, Process Solutions. “The versatility of the single-use PureFlex™ film has allowed it to be used throughout the entire production process, limiting validation and implementation effort. The enhanced PureFlex™ Plus film adds further robustness to our proven film technology, helping to ensure process container integrity even in physically stressful applications.”

Similar to its predecessor, PureFlex™ Plus film is a high purity, medical grade, coextruded film designed to provide strength, flexibility, low gas permeability, and an inert product contact layer. The fluid contact material is made of ultra low density polyethylene (ULDPE), the gas barrier layer is made of polyethylene vinyl alcohol copolymers (EVOH), and the first outer layer is made of ethylene vinyl acetate (EVA). All contact layers are free of animal-derived components and comply with the Food and Drug Administration regulation 21 CFR 177.1520. Using EMD Millipore’s EZ fold technology, these flexible films allow for high-volume bag assemblies (> 500 L) to be filled in a bin without operator manipulation or the use of a hoist.

PureFlex™ films are used in the construction of EMD Millipore’s Mobius® assemblies and NovaSeptum® sterile sampling products, which can be customized for any application. Business continuity plans have been established to ensure uninterrupted global supply of these films and products.

For more information please visit: http://www.emdmillipore.com/US/en/20140202_211107.

About EMD Millipore

EMD Millipore is the Life Science division of Merck KGaA of Darmstadt, Germany and offers a broad range of innovative, performance products, services and business relationships that enable our customers' success in research, development and production of biotech and pharmaceutical drug therapies. Through dedicated collaboration on new scientific and engineering insights, and as one of the top three R&D investors in the Life Science Tools industry, EMD Millipore serves as a strategic partner to customers and helps advance the promise of life science. Headquartered in Billerica, Massachusetts, the division has around 10,000 employees, operations in 66 countries and 2013 revenues of €2.6 billion.

EMD Millipore is a division of Merck KGaA, Darmstadt, Germany.



About Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Its subsidiaries in Canada and the United States operate under the umbrella brand EMD. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. The company generated total revenues of € 11.1 billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the name has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.