EMBEDDED PARTICLES IN SINGLE-USE FILMS: COSMETIC DEFECT OR INTEGRITY RISK?

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Key Words: Films, Gels, Particles, Integrity

Single-use films make up a large fraction of the surface area of single-use systems, and thus must meet stringent requirements not required for typical packaging films: high mechanical integrity and low levels of chemical leachables. Consequently, typical single-use films are relatively thick and contain much reduced levels of chemical additives (processing aids and stabilizers). Reduction of additives may result in a higher probability for finding gel particles embedded within the film. Gel particles, described as translucent unmixed or “un-melted” polymer resin perhaps with increased cross-linking or molecular weight, appear as “fish eye” shaped defects in the film. High temperatures within the extrusion process may chemically degrade gel particles, which then become amber, brown or black in color. In addition, the industrial scale and complex nature of film extrusion processes increases the risk for embedded foreign particle contamination in the film.

Are embedded particles in single-use films cosmetic defects, or do they represent significant risk to process reliability (process integrity) or risk to product purity? In an attempt to quantify risk to integrity, tensile testing, flexural durability testing, and a unique pressure burst test were applied to single-use films with varying type and size of embedded particles. For embedded gels, the results show that only extraordinarily large gels impact tensile test results, and only very large gels impact burst test results. Limited evidence shows similar effects for embedded foreign particles. After flexural durability testing, no pinholes were found even when multiple embedded gel particles were present in the film.

The test methods applied generate extreme stresses and strains compared to those found in real applications. In addition, the effects appear only with gels much larger than the detection capabilities of on-line inspection systems. Thus the risk of embedded particles to single-use film integrity appears low. Risk of embedded particles in film to product purity is addressed in a separate paper in this conference addressing overall particle contamination risk factors.