

## CELL GROWTH PERFORMANCE WITH A NEW SINGLE-USE FILM

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The biomanufacturing world has increasingly adopted single-use systems to achieve greater efficiency and productivity, reduce capital investment in facilities and equipment, and decrease risk of cross-contamination. Along with the many benefits, single-use technologies can also pose some risks. Polymers in single-use systems have the potential to introduce unwanted chemicals into the manufacturing process fluid. The anti-oxidant Irgafos 168® is commonly used in industry films. Hammond, et. al.<sup>1</sup> found that when oxidized Irgafos 168® is subjected to gamma irradiation, bis (2,4-ditert-butylphenyl) phosphate (bDtBPP) is formed. Studies have shown bDtBPP is a cell growth inhibitor even at low concentrations (ppm range) for CHO cells. Here we present an evaluation of the effects of Merck's new, Irgafos 168® free, multi-layer on cell growth and protein production.

A deep dive fed batch production study was performed with four recombinant CHO cells lines in order to investigate the effects of this newly developed film on cell culture performance and productivity. Similar growth patterns as well as highly similar protein titers were seen with all cell lines grown in media incubated with the new film as compared to glass. No negative effects were shown when using Merck's new film with any of the studied cell lines.

<sup>1</sup>Hammond M, Nunn H, Rogers G, Lee H, Marghitoiu AL, Perez L, Nashed-Samuel Y, Anderson C, Vandiver M, Kline S 2013, 'Identification of a leachable compound detrimental to cell growth in single-use bioprocess containers', *PDA J Pharm Sci Technol*, vol. 67, no. 2, pp. 123-134.