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A HOST CELL PROTEIN THAT MAY IMPACT POLYSORBATE DEGRADATION

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There is growing interest and concern related to host cell proteins. Current issues with host cell proteins include questions related to the various available analytical approaches and the sensitivity of those approaches as well as issues with purification strategies and the impact of host cell proteins downstream. The availability of a sequenced genome enables new opportunities to address problematic host cell proteins via cell line engineering. We studied difficult to remove host cell proteins in CHO cells with the goal of identifying host cell proteins that may be product associated with a number of monoclonal antibodies, that may copurify with products on various polishing resins, and that may significantly alter their expression as a function of cell age. We identified more than 120 potentially problematic host cell proteins. We believe that at least one of these problematic host cell proteins may contribute to issues in the degradation of polysorbates which are commonly used in monoclonal antibody formulations. Knockdown and knockout cell lines for this host cell protein do not demonstrate the same level of polysorbate degradation. This work was supported by the National Science Foundation.