

Technical Bulletin

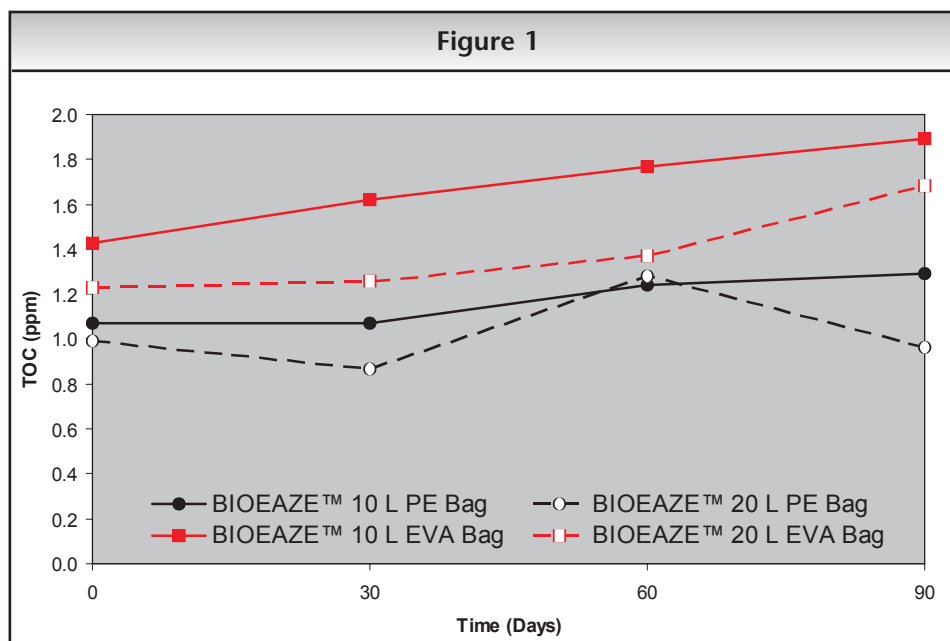
Total Organic Carbon (TOC) Testing of Cell Culture Grade Water Stored in BIOEAZE™ Polyethylene (PE) and Ethyl Vinyl Acetate (EVA) Bioprocess Bags

BIOEAZE™ Polyethylene (PE) and Ethyl Vinyl Acetate (EVA) bioprocess bags are designed to hold a variety of sterile liquids including cell culture media, water and buffers. SAFC Biosciences has performed extensive physical and chemical characterizations of these films, including Total Organic Carbon (TOC) testing. TOC testing provides an indirect measurement of organic impurities in water. Resins, polymers and solvents used during the manufacture of PE and EVA films have the potential to contribute small amounts of organic contamination.

The following study was undertaken to determine the quantity of TOC in Water — Cell Culture Grade (Catalog Number 59900C) stored in PE and EVA bags. The water meets all USP and EP criteria for Water for Injection (WFI). Sterile 10 L and 20 L PE and EVA bags were filled with the water under cGMP conditions. The bags were stored at 2 to 8 C for 0, 30, 60 and 90 days, at which time sterile samples were obtained.

The samples were tested for TOC using methods that meet the USP 643 and EP 2.2.44 monographs for WFI. All testing was performed by Aperio Scientific (Overland Park, Kansas, USA) using a Sievers® 900 Laboratory TOC Analyzer. The results (see Figure 1) indicate very low levels of TOC in water stored in PE and EVA bags. The levels of TOC in PE bags (0.9 - 1.3 ppm) were slightly lower than those obtained from EVA bags (1.4 - 1.9 ppm).

The intended use of this data is to provide quantitative chemical information to supplement a risk assessment of BIOEAZE™ bags. For further information regarding this study or BIOEAZE™ bioprocessing systems, please call our Technical Services department or e-mail technicalservices@sial.com



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