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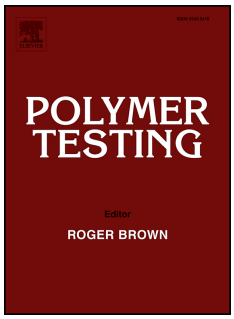

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ACCEPTED MANUSCRIPT

Chemical ageing effects on the mechanical behaviour of ethylene-propylene diene monomer

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Keywords: Ethylene-propylene diene monomer (EPDM); Ageing; Chemical degradation; Mechanical properties; Biopharmaceutical production

Abstract

Ethylene-propylene diene monomer (EPDM) elastomer diaphragm failures due to material degradation pose a major risk in the biopharmaceutical industry, as they can result in long periods of production downtime. It is suspected that a key cause of this EPDM degradation is due to the chemical solutions used in equipment cleaning processes. However this has never been empirically investigated in the public domain. Twenty four virgin samples were utilised for testing, twelve of which were subject to common chemical cleaning solutions used in the biopharmaceutical sector. The chemical solutions under investigation were aqueous solutions of NaOH, NaClO, H_3PO_4, and the interaction between 100°C H_2O and NaClO. The characterisation of the degradation process was conducted by mechanical testing. The results show that degradation of the polymer bulk proceeds predominantly via crosslinking for all exposure types. NaOH and H_3PO_4 exposure results in an accelerated rate of crosslinking compared to NaClO in the early stages of exposure.

1. Introduction

Ethylene propylene diene monomer (EPDM) is a rubber widely used as the dynamic sealing element in flow control valves in the biopharmaceutical sector. EDPM is therefore a product contact material, used to maintain the integrity of the hermetically sealed environments within production bioreactors. As part of biopharmaceutical production, intermittent clean-in-place (CIP) cycles remove product soils from all product contact surfaces via aqueous chemical solutions. The chemical solutions commonly used across the biopharmaceutical industry are NaOH, NaClO, and H_3PO_4. It is suspected that these chemical exposures have a degradative effect on the EPDM diaphragms. However, the potential effects these chemical solutions have on the mechanical properties of EPDM diaphragms has never been empirically investigated in the open literature.

The degradation of EPDM rubber has been extensively studied, the most commonly investigated mechanisms involving photo-degradation and/or thermo-degradation, both of which can be oxidative or non-oxidative [1–12]. Despite the vast literature studying photo and thermo degradation, there is scant literature on the effects of acidic and basic environments on the rate of EPDM composite degradation. McGrath et al [13] studied the accelerated aging of EPDM polymer insulators subjected to UV light and acid rain with a pH of 4.6. They concluded that due to the acid and UV exposures that surface roughening will occur. Mitra et al [14–16] and Nandakumar and Kurian [17] investigated the effect of 20% and 60% aqueous solutions of H_2SO_4 on EPDM rubbers, respectively. These studies concluded that acid induced chemical degradation of EPDM results in an initial decrease in crosslink density due to hydrolytic attack of the crosslink sites. Upon further exposure however, these oxygenated species lead to new crosslinks, and thus higher crosslink density.

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