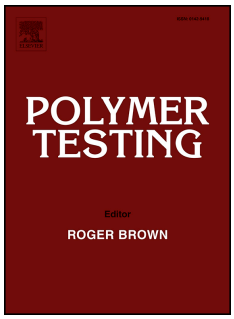
Accepted Manuscript



Shelf life of condoms

John Gerofi, Morten Sorensen

PII: S0142-9418(16)30813-3

DOI: 10.1016/j.polymertesting.2016.10.031

Reference: POTE 4811

To appear in: *Polymer Testing*

Received Date: 19 August 2016

Accepted Date: 26 October 2016

Please cite this article as: J. Gerofi, M. Sorensen, Shelf life of condoms, *Polymer Testing* (2016), doi: 10.1016/j.polymertesting.2016.10.031.

Product Performance

Shelf Life of Condoms

John Gerofi[a] and Morten Sorensen[b]

a Enersol Pty Ltd, 235 Nelson St, Annandale, NSW, 2038, Australia (jgerofi@enersol.com.au)

b. United Nations Population Fund, UN City, Marmorvej 51, 2100 Copenhagen, Denmark (sorensen@unfpa.org)

Abstract

Condom quality is, in many countries, regulated through ISO (international standard) 4074. It prescribes a maximum shelf life of 5 years and also a real time stability requirement to ensure the products are fit for use until the expiry date. This article reports on tests done on condoms well past their expiry date, as well as some which were near their expiry date and then submitted to the additional challenge of storage at 50°C for 90 days. The results show that, with two exceptions, the condoms continued to comply comfortably with the requirements of the standard. It thus appears that the 5 year maximum shelf life currently allowed for condoms should be reviewed.

Key-Words

condom, shelf-life, packaging, deterioration, inflation, tensile

1. Introduction

In a previous article[1], we summarized existing data on shelf life of condoms. The methods of predicting shelf life from accelerated aging data are of limited value. It appears that oven-conditioning at 50°C is the most reliable method currently known, and has been included in the 2014 and 2015 editions of ISO 4074[2],[3]. Nonetheless, ISO 4074 requires real time aging of typical lots of each product to verify shelf life claims. Despite these assurances, the standard arbitrarily limits shelf life to 5 years.

Compliance with ISO 4074 has become widely accepted as evidence that condoms are fit for use, for example under the European Medical Device Directive[4]. Even so, an in vitro trial to verify