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Product performance

Re-evaluation of data and requirements on condom shelf life

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ABSTRACT

Condom quality is, in many countries, regulated through ISO (international standard) 4074 which 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. The United Nations and other major public sector purchasers prescribe square packs made with aluminium foil. This article examines the history of, and available data on, the shelf life of condoms, and on how individual packs may affect that. It reviews data in the open literature, and that used in the development of the requirements in ISO 4074, and includes relevant data on the physical properties of condoms as a function of storage time. The change in properties is examined in the light of the 5 year shelf life limit, and the package materials and shape. The results indicate opportunities to relax the packaging and shelf life requirements on some of the products.

1. Introduction

The goal of the United Nations (UN) is to gradually become climate neutral and environmentally sustainable, as described in 'Greening the Blue' [1]. Specific environment goals are described in the Green Procurement Strategy [2].

The United Nations Population Fund, (UNFPA) is the largest public sector procurer of condoms. It uses the product specifications dictated by ISO 4074 [3] and the UNFPA-WHO publication The Male Latex Condom [4], which specify a maximum shelf life of 5 years, irrespective of how the condoms perform in practice. Allowing a longer shelf life would simplify the management of distribution networks and reduce waste. This article examines existing data to see whether current products retain adequate physical properties to justify a shelf life of longer than 5 years.

Previous experience with shelf life prediction indicates that no method of accelerated shelf life determination is 100% reliable and, therefore, ISO 4074 and the WHO/UNFPA specification require that shelf life be confirmed by a real time study. ISO 4074 requires that this be done at a constant temperature of 30 °C, based on a study by Grimm [5], which is widely used in the pharmaceutical industry. It was concluded that a mean kinetic temperature of 30 °C was adequate to simulate the most extreme storage conditions likely to be encountered.

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The Male Latex Condom also requires condoms to be packed in square aluminium foil packs. Relaxation of this restriction could reduce the environmental impact of the packaging.

This article reviews available data on the physical properties of condoms as a function of time.

2. What is shelf life?

A logical definition of shelf life would be the time from manufacture after which the products would no longer be safely usable. The most important properties of the condom are those connected with its strength and freedom from holes. Other issues such as persistence of lubricant on the surface, package integrity and appearance also play a role.

Condom standards put an arbitrary upper limit of 3 or 5 years on the shelf life, via the expiry date. The 2002 edition of ISO 4074 defined the expiry date as the date after which the condom should not be used, and the shelf life as the time from the date of manufacture to the expiry date. The standard also made recommendations for inferring provisional shelf life from accelerated studies using elevated temperatures and the Arrhenius equation.

Subsequently generated data indicated that this process did not give reliable results, but the equation is still used to give a first guess at the dependence on temperature of chemical reaction rates. The 2002 edition of ISO 4074 also required real time data to make a final shelf life determination.

The 2014-15 [6,7] standards define shelf life as the period for which condoms are required to conform with the inflation, freedom from holes and package seal requirements of the standard. The 2002 definition of expiry date remains in force, and is thus technically unrelated to the shelf life in terms of ISO 4074.

The 2014 standard thus provided the first measurable criterion for shelf life. It also provided a provisional link between accelerated and real time aging, suggesting that 6 months' storage at 50 °C was provisionally equivalent to about 5 years at 30 °C, the temperature prescribed for mandatory real time shelf life testing. There is an implicit assumption that condoms which meet the ISO 4074 requirements are fit for use, except that currently the 5 year limit on shelf life remains in parallel with the physical requirements.

3. Survey of available literature

Traditionally, the rubber industry has used oven conditioning at 70 °C to simulate aging. A correlation was established [8] for samples 2 mm thick, but its applicability to thin articles is not established. In early condom standards, tensile testing after oven conditioning was implicitly the norm for assessing adequate shelf life. There were no formal correlations available, and different standards used different exposure times at 70 °C, from 24 h to 1 week.

Systematic studies of condom deterioration and shelf life began to appear in the 1980s. These studies were primarily undertaken by PIACT (PATH) and focussed on simulation of condom aging by exposure to UV light, which in turn generates ozone [9,10]. Condoms which had been exposed to UV light were more likely to break in use. This information was the basis for current restrictions on transparent packing for condoms.

Subsequently, PATH made an extensive study of condom shelf life [11]. When PATH's study was beginning, WHO produced its specifications for condoms [12]. WHO took a cautious approach, requiring square packs made with a laminate including at least 8 μm of aluminium foil.

Around 1990, ISO TC 157 (the ISO technical committee responsible for condom standards) began to take an increased interest in condom shelf life prediction, and established Working Group 13 to develop a predictive test of shelf life. It began by studying data supplied by various manufacturers and PATH. This information is the richest single source of information on condom shelf life.

3.1. ISO TC 157 working group 13 documents

This working group collected information on all matters related to condom shelf life. Information available to the working group masked the names of the manufacturers of the condoms. Some of the key documents are discussed below.

3.1.1. A summary of existing data, done in 1997 [13]

3.1.1.1. Packaging-from PATH. Unpackaged, unlubricated condoms were more affected by air than packaged ones. Burst pressure effectively fell to 0 after 70 days at 70 °C for unpackaged condoms.

At 45 °C, the burst volume of packaged condoms decayed more slowly than that of unpackaged ones. Volume began to drop off after about 8 months – unpackaged dropped quicker than packaged. Elongation at break changed very little.

One of PATH's submissions [14] to ISO TC 157 WG 13 showed that at 45 °C, condoms in plastic packs had a much faster decline in burst pressure than condoms in aluminium foil packs.

3.1.1.2. Condom shelf life - manufacturer A. The behaviour of 4 products was studied at room temperature (in Japan). Mean burst volume decayed monotonically by about 25% over 10 years. Mean pressure peaked at 1.9–2.4 L after about 3 years, and returned to its original value after 10 years.

3.1.1.3. JISC data. Information on one lot was submitted, including real time for 5 years, 7 days at 70 °C and 90 days at 45 °C. The real time data showed relatively stable volume with a slight increase in the 5th year (5% from the initial value). The pressure was also relatively stable with a slight decrease in the fifth year (12% from the initial value).

3.1.2. Summary by manufacturer [15]

The original summary covered 5 manufacturers, of which the relevant items are summarized below.

Mfr 1 presented real time data, plus 40 °C and 100% humidity for 4 years and 70 °C for 2 and 9 days. Mfr 1 did the real time study in climate zone II or III (sic). There were 2 types of pack, both square with silicone lubricant, one with aluminium foil, one plastic.

Comparison of tensile and inflation properties suggests equivalent behaviour until 3.5 years, for all cases. At the last data point, 4 years, it appeared that the force at break and burst volume may be declining for the products kept at 40 °C. 40 °C for 4 years is far more challenging than one would find in any condom storage facility world-wide, and could be considered roughly equivalent to about 8 years at 30 °C. The results are presented graphically in Figs. 1–4.

The products kept at ambient conditions showed a steady decline in all physical properties except burst pressure, which increased slightly. There was very little difference between the plastic and aluminium packs, as the graphs show. At 4 years, the products kept at 40 °C showed a decline in force at break.

Mfr 3 presented 5 years' real time data from climate zone 1 (temperate). The pack shape was not given. There were 9 lots of which 3 had N9 lubricant. There were 3 lots with a cellophane laminate, and 3 with an aluminium-plastic laminate. There was very little discernible difference in the behaviour of the 2 types of packing.

Mfr 4 [16] submitted data on three lots of product lubricated with silicone fluid, with real time aging over 5 years as well as 90 days at 45 °C. In the real time case, the volume dropped by 28%–30% and the pressure changed by −4% to 17%. At 45 °C, the mean volume dropped by 11–18% but the pressure increased by 13–17%.

The manufacturer also submitted information on 2 additional batches, which were lubricated with PEG 400 and nonoxynol. Two different foils were used, but their composition was not stated. This product was conditioned at 20 °C, 30 °C and 40 °C for 5 years. Both batches appeared stable for 5 years at 20 °C. At 30 °C, one of the packages showed a drop in both mean volume and pressure, but it appeared that both would pass the ISO requirements. At 40 °C, both packages showed little change in burst volume, but a decrease in pressure (still apparently within ISO requirements).

Mfr 5 (ISO WG 13 doc N 19) [17], based on tests after storage at elevated temperatures, reported as follows:

> "The major conclusion is that our condoms appear to be indefinitely stable at 50 °C and even at 60 °C show very little evidence of degradation based on air burst pressure. There appears to be no difference in stability between condoms in plastic and aluminium foils. If anything, the plastic foil appears to be better".

This conclusion is based on tests conducted over 112 days, using 50, 60, 70 and 80 °C. 112 days at 50 °C shows a slight increase in burst pressure and a 5% decrease in burst volume for the Al foil and a 3.4% decrease for the plastic pack. Even at higher temperatures, there is relatively little difference between the plastic and aluminium.