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Additional lubricants for male natural rubber latex condoms — Effect on condom strength

Lubrifiants supplémentaires pour préservatifs masculins en latex de caoutchouc naturel — Effet sur la résistance du préservatif

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 19671:2018 incorporates the following corrections:

— specifications for viscosity and specific gravity of positive control in 6.2;

— specifications for viscosity and specific gravity of positive control in Clause 9;

— "test substance" has been replaced by "lubricant" in A.3.3;

— subscript in Formula (B.4).

Introduction

Weakening of natural rubber latex is known to occur after contact with certain lubricants, particularly petroleum-based products. This procedure was developed as a screening method for lubricant manufacturers to determine whether or not a particular personal lubricant or topical medicine has a significant effect on the tensile and airburst properties of condoms. It is also applicable to topical medicines and other chemicals that might come in contact with vulval, vaginal or rectal tissues, and hence with condoms.

The method is designed for use on male condoms that meet the criteria of ISO 4074. While the test method can be effective for male condoms made of other raw materials, there is no evidence upon which to base pass/fail criteria for these materials.

This test method does not determine the safety of either the test substance or the condom.

This test method is to be used only to determine if the tensile or airburst properties of the condom have been significantly affected by the test substance.

Additional lubricants for male natural rubber latex condoms — Effect on condom strength

1 Scope

This document specifies a method of assessing the effect or compatibility of an additional or personal lubricant with lubricated male natural rubber latex condoms. It also applies to topical medicines and any other substances that come into contact with such condoms. It describes the measurement of changes in physical properties of the condoms after exposure to the test substance (i.e. lubricant, topical medicine, etc.) and specifies the pass/fail criteria for such changes.

This document is not applicable to the assessment of the compatibility of lubricants applied to a condom at the time of manufacture. It is not directly applicable to the assessment of the compatibility of a particular condom with lubricants or other substances. It is not directly applicable to tests using female condoms, although similar principles can apply.

The test methods are applicable to condoms made from natural rubber latex and from synthetic materials, but a pass/fail criterion is only stipulated for natural rubber latex.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4074:2015, *Natural rubber latex male condoms — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4074 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
personal lubricant
additional lubricant intended for application by the user at the time of condom use

3.2
positive control
test substance (3.3) which is known to cause deterioration in the physical properties of a condom

3.3
test substance
lubricant (3.1), *topical medicine* (3.4) or other material which is being tested for compatibility with condoms

3.4
topical medicine
medicine intended to be used vaginally or rectally, and which might come into contact with a condom in use

4 Principle

This test method measures the change in tensile properties and inflation properties of condoms, after 60 min of contact with a lubricant or other test substance to which this document refers. Force at break is the principal and most sensitive variable used in assessing the effect of test substances.

For tensile testing, rings cut from condoms are exposed to the test substance, heated to body temperature, cleaned of excess test substance, and tested for force at break and percent elongation at break in accordance with Annex A. Those properties are compared to control rings that are subjected to the same procedures using distilled water instead of the test substance.

For inflation testing, the parts of the condoms which are subject to inflation are exposed to the test substance and are then heated to body temperature. They are then subjected to inflation testing as prescribed in ISO 4074 or ISO 23409. The results are compared to control condoms that are subjected to the same using distilled water instead of the test substance.

5 Apparatus

5.1 Environmental chamber or oven, capable of maintaining (40 ± 2) °C.

5.2 Specimen containers for inflation testing, capable of holding one condom and sealing volatile components of the test substance, so they cannot escape into the atmosphere. The excess space in the container should be kept to a minimum.

NOTE A glass jar is a suitable container.

5.3 Specimen containers for tensile testing, capable of holding one tensile sample and sealing volatile components of the test substance, so they cannot escape into the atmosphere. The excess space in the container should be kept to a minimum.

NOTE A glass jar is a suitable container.

5.4 Tensile tester and roller grips, capable of testing ring specimens according to Annex A.

5.5 Ring-cutting die, mechanical press, and replaceable cutting surface, for cutting ring specimens from condoms, compliant with Annex A.

5.6 Mounts, suitable for holding ring samples while they are being coated with test substance. These mounts may be two cylindrical rollers about 15 mm in diameter, placed with their axes about 50 mm apart, over which the samples are stretched. Refer to Annex A.

5.7 Soft paintbrush, suitable for spreading the test substance on the condoms. A width of approximately 10 mm and thickness 5 mm to 10 mm, is recommended.

5.8 Cylindrical mounts, suitable for coating and storing condom samples for inflation testing. These can be glass test tubes 32 mm to 38 mm in diameter, or plastic rods with approximately hemispherical ends, mounted in such a way that the condoms can easily be unrolled onto them.

NOTE The tubes are intended to produce a smooth condom surface for applying the test substance, and also to allow easy removal of the condom after coating. The dimensions are not critical.

5.9 Inflation tester, suitable for testing condoms in accordance with ISO 4074:2015, Annex H.

5.10 Syringes or pipettes, for dosing 1,5 ml and 0,2 ml of the substance under test.

5.11 Small beaker or cylindrical container, about 30 mm in diameter, for storing the test substance and for moistening paintbrushes.

6 Materials

6.1 Condoms, complying with ISO 4074, to which the test substance is applied. The condoms shall be smooth and parallel-sided. The mean thickness of the condoms used, when measured according to ISO 4074 shall be between 0,055 mm and 0,07 mm. The mean force at break of the negative control condoms shall be between 70 N and 100 N.

6.2 Liquid paraffin, for positive control testing, meeting the current requirements of the US, European or British pharmacopeia, with a specific gravity of 0,83 to 0,85 at (25 ± 2) °C, and a kinematic viscosity of $4{\cdot}10^{-5}$ m^2/s to $5{\cdot}10^{-5}$ m^2/s at 40 °C. The liquid paraffin is expected to cause significant degradation in natural rubber condom physical properties when the test method is properly performed.

6.3 Cyclomethicone D5, for positive control testing, meeting the current requirements of the US, European or British pharmacopeia. The cyclomethicone D5 is expected to cause significant reversible, short-term degradation in natural rubber condom physical properties when the test method is properly performed.

6.4 Distilled water, for negative control testing.

6.5 Solvents, including water, isopropanol (IPA), and mild detergent, for cleaning laboratory equipment and supplies after each test substance group has been tested.

6.6 Cornstarch, or similar inert powder, to assist in dimensional measurements and tensile testing (optional).

6.7 Low-lint laboratory-grade paper towels, for removing test substance from test samples after oven conditioning.

7 Samples and tests

7.1 Sample overview

7.1.1 This test method shall be performed on three distinct, commercially available natural latex condoms made in different factories and belonging to different independent companies. The products shall be chosen from among leading brands in the country or countries where the test result is to be applied or, in the case of internationally branded products, three major international brands. The mean thickness for each product as determined in accordance with ISO 4074 shall be in the range 0,055 mm to 0,07 mm.

7.1.2 Each brand of condom should be lubricated, straight-walled, smooth condoms from a single finished lot.

7.1.3 All natural rubber latex condoms shall meet the requirements of ISO 4074.

It is acceptable to purchase condoms that are stated to conform to ISO 4074 from retail outlets or wholesalers.

7.2 Condom sample groups

7.2.1 Each of the three distinct brands of condoms shall be divided into two groups and tested for physical properties in the following order:

a) Control group: Condoms are tested according to 8.3 and 8.4, but the tensile samples/condoms are lubricated with distilled water. All other handling and testing of the control tensile samples/condoms shall be exactly the same as for the test substance group. There is no contact with the test substance in the control group.

b) Test substance group: Condoms are tested in accordance with Clauses 8 and 9 with a substance for which condom compatibility is unknown.

7.2.2 For staff training and for periodic re-validation of the method, a third group of products exposed to a positive control (with short or long-term effects) shall be tested, either instead of or after, the test substance group.

7.3 Sample size

The sample size for tensile testing shall not be less than 30 condoms per group.

7.4 Quantity of test substance

7.4.1 Inflation testing

a) Lubricants: Each condom shall be exposed to (1,5 ± 0,15) ml of lubricant.

b) Topical medicines: Each condom shall be exposed to one normal dose of the medicine. Where necessary to achieve even spreading over the sample, the medicine may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of up to 45 °C prior to application.

7.4.2 Tensile testing

a) Lubricants: Each ring sample shall be exposed to (0,2 ± 0,02) ml of lubricant.

b) Topical medicines: Each ring sample shall be exposed to (12 ± 1) % of one normal dose of the medicine. Where necessary to achieve even spreading over the sample, the medicine may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of up to 45 °C prior to application.

8 Procedure

8.1 General

The negative control test shall be performed first, and be followed immediately by the test on the test substance. Additional substances may be tested thereafter, provided all equipment is thoroughly cleaned of the previous test substance beforehand. Provision is made for testing positive controls, liquid paraffin and cyclomethicone D5, to train operators and validate techniques.

NOTE Some regulatory bodies might require positive control results to be submitted along with the results for the test substances.

Tests performed using natural latex condoms shall apply to claims of compatibility with natural latex condoms only.

Tensile testing shall be conducted in accordance with Annex A.

8.2 (Negative) control testing

For both inflation and tensile testing, a control test shall be conducted immediately before using the test substance. For negative control testing, distilled water shall be used in the same quantity as required for the test substance.

Condoms are tested according to 8.3 and 8.4, but the tensile samples/condoms are lubricated with distilled water. All other handling of the control tensile samples/condoms shall be exactly the same as for the test substance group. There is no contact with the test substance in the control group.

8.3 Inflation testing

For each of the product groups, mount 30 samples on suitable cylindrical mandrels. The mandrels should be marked with a line indicating 150 mm from the hemispherical top. If the mandrels are not so marked, or the mark is not clearly visible through the condom, make a mark on the condom itself, 150 mm from the top of the mandrel. Use a spirit-based marker.

If the test substance is too thick to spread easily on the condom, it may be heated to a maximum of 45 °C before application. Where necessary to achieve even spreading over the sample, topical medicines may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of up to 45 °C prior to application.

Wet the paintbrush with the test substance using the storage container, and drain it by brushing it against the lip of the container. Apply the required quantity of test substance or control substance using a syringe or pipette, while spreading it with the brush on the outer surface of the condom at the same time, between the closed end and the 150 mm mark. Immediately after application of the test substance, remove the condom from the mandrel by sliding the bead slowly upwards (this will wrinkle the condom), then place it in the specimen container. Seal the container immediately.

Syringes are more convenient to use where possible, but the seals may be affected by some test substances Pipettes or burettes may be used instead of syringes.

When a sub-group of condoms has been coated, place them immediately in an oven or environmental chamber at a temperature of (40 ± 2) °C. Leave the samples in the oven for (60 ± 5) min, then remove them.

Open one of the specimen containers and immediately wipe the condom contained in it with a fresh paper towel. Without delay, place the condom on the inflation tester and perform an inflation test on that sample. Repeat for all other condoms in the sub-group.

Cornstarch or similar inert powder may be used to assist in handling the condoms for testing after oven conditioning

Record the number of samples, the type of test substance or control substance applied, and the burst volume and pressure as required in ISO 4074.

Repeat the process until all condoms have been tested.

8.4 Tensile testing

Cut and measure a tensile ring sample from each of 30 condoms in accordance with Annex A. Place each sample on a suitable mount, so that the entire circumference of one side of the sample can be coated with the substance being tested. Wet the paintbrush with the test substance using the storage container and drain it by brushing it against the lip of the container. Apply the required quantity of test substance or control substance to the outside of the ring sample using a syringe or pipette, while at the same time spreading it with the brush.

Syringes are more convenient to use where possible, but the seals may be affected by some test substances. Pipettes or burettes may be used instead of syringes.

If the test substance is too thick to spread easily on the condom, it may be heated to a maximum of 45 °C before application. Where necessary to achieve even spreading over the sample, topical medicines medicine may be dissolved or dispersed in a minimum quantity of distilled water at a temperature of 45 °C prior to application.

Immediately after application of the test substance, remove the sample from the holder, and place it in a specimen container. Seal the container.

When a sub-group condom ring samples has been coated, place them immediately in an oven or environmental chamber at a temperature of (40 ± 2) °C. Leave the samples in the oven for (60 ± 5) min, then remove them.

Cornstarch or similar inert powder may be used to assist in handling the samples for testing after oven conditioning.

Open one of the specimen containers and immediately wipe the sample contained in it with a piece of clean paper towel to remove excess test substance. Place the sample on the tensile tester immediately after wiping and. perform a tensile test on that sample. Repeat for all other condoms in the sub-group.

Record the number of samples, the type of test substance or control substance applied, and the force at break and elongation for each sample.

9 Positive control testing

For method validation, a test shall be conducted using a positive control substance for both medium term and immediate effects before doing tests on unknown test substances.

Tests using positive controls shall be conducted every time there is any change made to the equipment used or to the procedures. The test procedure is as outlined in Clause 8, with the positive control substances used instead of the test substances.

Positive control testing should also be part of the training programme for these tests, each operator should conduct at least one series of tests with positive control substances.

Some regulatory bodies might require results for positive control samples to be submitted routinely along with test results to confirm that the test procedure has been conducted properly. It is recommended that positive controls are included in any test where the results may be submitted to such a regulatory authority or notified body.

The following control substances shall be used for natural rubber condoms.

a) For medium term effects, liquid paraffin meeting the current requirements of the US, British or European pharmacopeia, with a specific gravity of 0,83 to 0,85 at (25 ± 2) °C, and a kinematic viscosity of $4 \cdot 10^{-5}$ m^2/s to $5 \cdot 10^{-5}$ m^2/s at 40 °C.

b) For immediate effects, cyclomethicone D5 meeting the current requirements of the US, British or European pharmacopeia.

10 Pass/Fail criteria

The procedure is based on comparing the properties of the condoms treated with the test substance with those of control condoms that have been through the same treatment process using distilled water in place of the test substance. The ratio of the mean properties of the treated condoms divided by the mean properties of the control condoms expressed as a percentage are used for this comparison. It is assumed that if the whole of the 95 % confidence interval for the percentage ratio falls within the range 80 % to 120 %, the condom and test substance have adequate compatibility.

The force at break properties are assessed first and these are used as the primary indicator of test substance/condom compatibility.

a) Determine the mean and standard deviation for each combination of condom type and test substance including the negative and, if appropriate, positive control results.

b) For each property, calculate the ratio of the mean values for the condoms treated with each test substance divided by the mean values for the negative control results and multiply the answer by 100 to determine the percentage ratios. Do this calculation for each test substance/condom combination including the results for the positive control if used.

c) For each property, calculate the 95 % two-sided confidence interval for the percentage ratios determine in step 2 above. The procedures for doing this calculation along with examples are given in Annex B.

d) Assess the statistical and practical implications of the percentage ratios determined in steps 3 and 4 using the following criteria:

   1) If the whole of the 95 % confidence interval for the percentage ratio falls within the range 80 % to 120 %, it can be assumed that the condom and test substance have adequate compatibility.

      NOTE 1 If the upper 95 % confidence interval for the percentage ratio equals or exceeds 100 % and the lower 95 % percentage ratio is equal to or is less than 100 %, then there has been no statistically significant change in properties at the 95 % confidence level.

   2) If the whole of the 95 % confidence interval for the percentage ratio lies below 80 % or above 120 %, it can be assumed that the condom and test substance do not have adequate compatibility.

      NOTE 2 It is unlikely that the lower 95 % confidence limits for force at break and burst pressure will exceed 120 % but if they do this does not necessarily indicate that the effectiveness of the condom will be compromised. If the lower 95 % confidence limits for elongation at break and burst volume are greater than 120 %, however, this might be indicative of a deterioration in the effectiveness of the condom.

   3) If the 95 % confidence interval for the percentage ratio includes 80 % or 120 % then the results are inconclusive. It may be possible to reduce the size of the 95 % confidence intervals by repeating the tests using larger sample sizes and so reach a conclusion based on a) or b) above. If the mean values for the percentage ratios are less than 80 % or greater than 120 % then it likely that repeat testing using larger sample sizes will confirm that the condom and test substance are not compatible. If the mean values for the percentage ratios are within the range 80 % to 120 % then repeat testing with larger sample sizes may show that the condom and test substance do have adequate compatibility.

Figure 1 shows example of various outcomes and conclusions.

If the percentage ratios are very close to the limits indicated in the guidelines above, it is permissible to repeat the testing using larger sample sizes to improve the level of discrimination of the tests. Larger sample sizes reduce standard errors and improve the reliability of the assessment.

A substance is deemed compatible with natural latex male condoms if the ratios of the force at break comply with compatibility requirements above for each of the three condom brands tested.

Where there is doubt about the interpretation of the results, or if a regulatory authority requires the data, it is possible to examine also the behaviour of the burst volume. This analysis is done in the same way as that for the force at break.

NOTE 3 The limits of 80 % to 120 % are primarily based on the analysis of results from interlaboratory trials for force a break on condoms exposed to various commercial lubricants and positive controls.

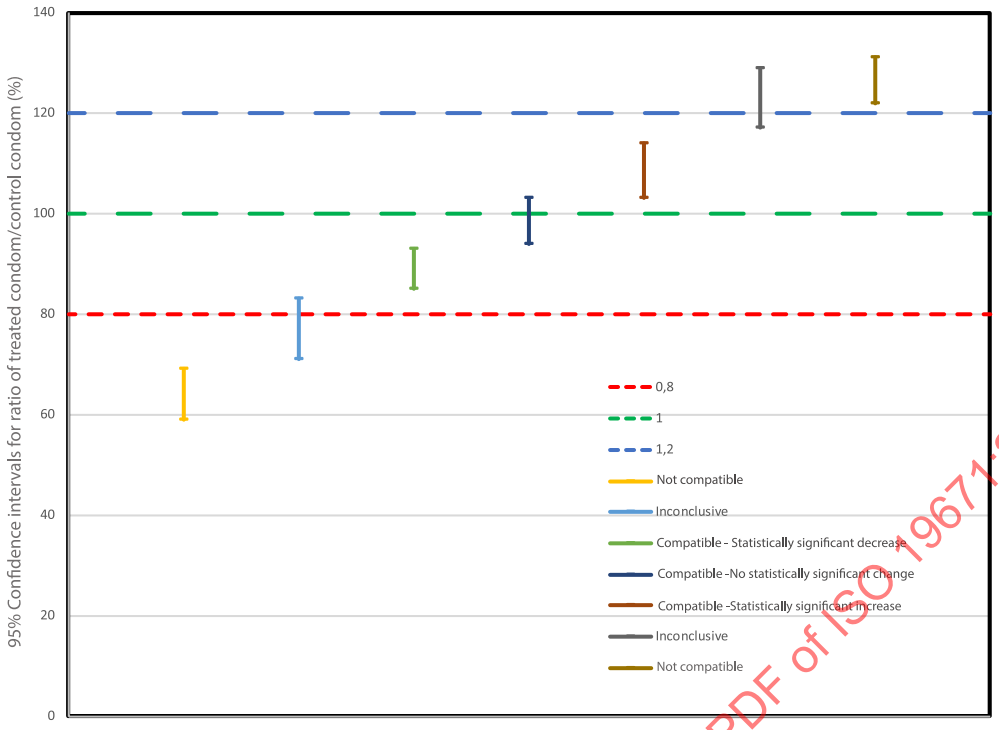

Figure 1 — Interpretation of confidence intervals for ratios

11 Expression of results

Record the number of samples used, and the test and control substances.

Record the force at break of all tensile samples tested.

Record the burst volume of all inflation samples tested, if this test is required.

Calculate the mean and standard deviation of all the parameters measured.

Report the ratio of each parameter, after exposure to that without exposure, and the 95 % confidence interval of the ratio.

Annex A
(normative)

Determination of force and elongation at break of test pieces of condoms

A.1 General

A test piece is cut from a condom and stretched until it breaks; the force and elongation at break can be measured.

A.2 Apparatus

A.2.1 **Cutting die**, consisting of two parallel knives (20 ± 0,1) mm apart set in a press above a suitable board. The length of the cutting edge of each knife should be not less than 70 mm.

A.2.2 **Tensile testing machine**, capable of an essentially constant rate of traverse and complying with the following requirements:

a) the normal sample grips are replaced by 15 mm diameter rollers, one free to rotate on a bearing, and the other driven by a small electric motor at a speed of approximately 7 r/min;

b) capable of equalizing the stress within a specimen by rotating one roller mechanically at a rotation frequency of approximately 7 r/min;

c) capable of determining the breaking load in the range 0 N to 200 N. The maximum permissible values; accuracy ±1 %, repeatability 1 %, reproducibility 1,5 %, zero ±0,1 N and with a machine resolution of 0,5 % of the maximum force;

d) having a roller separation speed of (500 ± 50) mm/min;

e) having manual or preferably automatic recording of the separation distance of the rollers and of the load during the test.

Further information on test equipment for rubbers and plastics is given in ISO 5893.

A.3 Preparation of test specimen

A.3.1 Move the condom inside the package such that it is away from the area where the package is to be torn. Tear the package and remove the condom.

Do not use scissors or other sharp instruments to open the package.

A.3.2 Unroll the condom ensuring that it is not excessively stretched in any direction.

A.3.3 To prevent sticking and to allow the cutting of a good test specimen, an absorbent powder such as cornstarch may be added to the condom or the lubricant may be removed using a suspension with a mass fraction of 2 % cornstarch in propan-2-ol followed by air drying.

A.3.4 Lay the condom flat with its length at right angles to the cutting edge of the die (A.2.1). Obtain the test piece by cutting the condom with one stroke of the press, if possible taking the test piece from a

parallel-sided, non-textured region including the portion 80 mm from the open end. If the portion 80 mm from the open end is not parallel-sided or is textured, take the test piece from an adjacent parallel-sided, non-textured region. If no region of the condom is parallel-sided and non-textured, take the test piece from the region 80 mm from the open end.

A.3.5 Lay the test piece flat and put the ruler on top and measure to the nearest 0,5 mm, the distance between the two folded edges.

Each sample should be inspected before testing to make sure that there are no nicks or other edge defects that could give rise to poor results.

A.4 Procedure

A.4.1 Carry out the test under controlled temperature of (25 ± 5) °C.

A.4.2 Place the test piece over the rollers of the tensile testing machine (A.2.2) and stretch it until it breaks.

A.4.3 At break, record the load, to the nearest 0,5 N, and the separation distance between the centres of the rollers to the nearest millimetre.

A.5 Calculation of results

A.5.1 Calculate elongation at break (E) as a percentage for each test piece by using Formula (A.1):

$$E = \frac{l_1 + 2d - l_2}{l_2} \times 100 \qquad \text{(A.1)}$$

where

l_1 is the length of the test piece in millimetres, rounded to the nearest millimetre, in contact with the rollers (equal to 47 mm with rollers of 15 mm diameter);

d is the final distance in millimetres between the centres of the rollers;

l_2 is the original perimeter of the test piece in millimetres (twice the distance obtained in A.3.5).

Round the result to the nearest 10 %.

A.5.2 If it is required to calculate the tensile strength, then the following formulae may be used.

When the thickness is determined by the mass method, the tensile strength, σ, expressed in megapascals (MPa) is given by Formula (A.2):

$$\sigma = \frac{F_b \rho l}{m} \qquad \text{(A.2)}$$

where

F_b is the force at break in newtons (N);

ρ is the density of rubber (0,92 g/cm^3);

l is the distance in millimetres between the two folded edges length of the test piece as determined in A.3.5;

m is the mass in milligram of the test piece.

When the thickness is determined directly by the micrometer method, the tensile strength, σ, expressed in megapascals (MPa) is given by Formula (A.3):

$$\sigma = \frac{F_b}{2wt} \tag{A.3}$$

where

F_b is the force at break in newtons (N);

w is the mean width of the test piece in millimetres (20 mm if the die specified in A.2.1 is used);

t is the thickness in millimetres of the condom.

Round the result to the nearest 0,1 MPa.