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Compatibility of lubricants with synthetic male condoms

Compatibilité des lubrifiants avec les préservatifs masculins en matière synthétique

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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 document 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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systematic contraceptive 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.

Introduction

Weakening of natural rubber latex is known to occur after contact with certain lubricants, particularly petroleum-based products with relatively low molecular weights.

Similarly, lubricants can affect condoms made from other materials.

This specification was developed to assist in developing methods 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 made from synthetic materials. It is also applicable to topical medicines and other chemicals that might come in contact with vulval, vaginal, oral or rectal tissues, and hence with condoms.

Strictly, the tests described in this document only show the compatibility of a specific lubricant with a specific condom relating to a suitable baseline product (lubricant/control). However, depending on the purpose of those tests, one can generalize the results to similar condoms or lubricants.

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

This test method is intended to determine if the tensile or airburst properties of the condom have been significantly affected by the test substance. It is generally assumed that materials that adversely affect the physical properties of the condoms to a material extent will cause additional failure in use, although that has not been determined clinically.

Some substances used as additional condom lubricants contain volatile fractions which may affect condom strength when they are first applied, but then evaporate rapidly. The condom's strength may (or may not) change again as a result. Depending on the duration of this effect, it may affect the condom's performance in use. Typical candidate substances that can transiently weaken a condom (depending on the condom material) include Cyclomethicone D5, lighter volatile fractions and phenyl trimethicone. Conversely, heavier volatile silicone fractions can be protective until they evaporate.

Condoms made from synthetic polyisoprene behave similarly to natural latex condoms, and may be tested according to ISO 19671.

Compatibility of lubricants with synthetic male condoms

1 Scope

This document provides guidance on assessing the effect or compatibility of an additional or personal lubricant with synthetic male condoms (excluding synthetic polyisoprene 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 intended to be used for evaluating the compatibility of chosen additional lubricants or topical medicines with chosen synthetic condoms. Each lubricant type is evaluated specifically against each condom material for which compatibility is claimed.

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 female condoms, although similar principles can apply.

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, *Natural rubber latex male condoms — Requirements and test methods*

ISO 19671, *Additional lubricants for male natural rubber latex condoms — Effect on condom strength*

ISO 23409, *Male condoms — Requirements and test methods for condoms made from synthetic materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4074, ISO 23409 and the following apply.

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

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

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

3.1
benchmark substance
readily available substance causing little change in the condom's physical properties against which the test substance's effect on the condom may be compared,

3.2
negative control
test substance (3.6) which is known to cause no change in the physical properties of the condom being evaluated

3.3
personal lubricant
additional lubricant intended for application by the user at the time of condom use

3.4
positive control
test substance (3.6) which is known to cause deterioration in the physical properties of the condom being evaluated

3.5
synthetic material
any base material other than 100 % natural rubber latex that is used to make condoms

3.6
test substance
personal lubricant (3.3), *topical medicine* (3.7) or other material which is being tested for compatibility with condoms

3.7
topical medicine
medicine intended to be used on the skin of the genital area, vulvally, vaginally, orally 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 synthetic condoms, after 60 min of contact with a lubricant or other test substance to which this document refers. This period of exposure has been chosen as being longer than the expected length of use of male condoms. For female condoms (not specifically covered by this specification), which can be inserted well before any sexual activity, an exposure time of 3 h should be considered.

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 a negative control or benchmark substance instead of the test substance.

For inflation testing, the parts of the condoms which are subject to inflation in the inflation test are exposed to the test substance and are then heated to body temperature. The condoms are then subjected to inflation testing as prescribed in ISO 23409. The results are compared to control condoms that are exposed to a negative control or benchmark substance in the same way instead of the test substance.

In ISO 19671, the approach taken is to check the compatibility of a particular lubricant with male latex condoms in general. In that case, 3 different products are required, and their design properties are constrained to be representative of typical, widely manufactured condoms. They are thus neither excessively thick or thin, and have no texture. A range for their tensile strength is also specified.

In the case of synthetic condoms, the range of different products available is much narrower than that of natural latex condoms. On the other hand, unlike male latex condoms, several different base materials may be used. In many cases, therefore, there will only be one or two products from each base material on any particular market. In some cases, although two products are made from the same class of materials (e.g. polyurethane) there can be different subclasses, and/or different methods of processing that result in quite different physical properties and susceptibilities. It will often not be possible, then, to draw conclusions about the applicability of a particular test substance to a class of condom base materials.

Unless uniformity of material properties across condom products is established beforehand by means of documented information, it is recommended that the test procedure outlined below be applied for a specific test substance and every relevant specific synthetic condom product.

If a group of condom products from the same base material is shown to behave identically, then it is acceptable to assess the compatibility of that group with a particular lubricant. In that case, the criteria for determining the range of condoms for which the results apply should be documented and included with the results of the tests.

The test apparatus and methods outlined in this document shall be identical to those required in ISO 19671.

The essential principle of the test is to compare the tensile and/or inflation properties of the condoms when treated with the test substance with those properties when the condoms are treated with the negative or benchmark control. In ISO 19671, the negative control stipulated is distilled water, and it is assumed that it has no effect on the physical properties of the condoms. In fact, hydration of the rubber film may well have a small effect on physical properties.

In many cases, distilled water is a suitable negative control for synthetic condoms, but there can be instances of condoms made from synthetic materials which are adversely affected by water. One example is condoms made from water-borne polyurethane dispersions.

Where distilled water does not constitute a negative control, the manufacturer of the condoms is encouraged to include this information in the product data sheet, and to recommend a suitable negative control or benchmark control substance.

For the purposes of this document, a benchmark control substance is one that may have a deleterious effect on the physical properties of the condom, but the effect is small enough to leave the condom fit for purpose in use. Condoms that conform to ISO 23409 shall have been subjected to a clinical trial, and shown satisfactory slippage and breakage in use, even though there may have been some weakening by contact with body secretions.

The human body is more than two thirds water by weight. Bodily fluids contain water, and the condoms themselves need to be relatively unaffected by the fluids they are likely to encounter in human use. Many bodily fluids are slightly saline. Normal (physiological) saline is a 0,9 % solution of sodium chloride in distilled water. It is isotonic with blood and other body fluids. Sodium ions are the main electrolytes in extracellular fluid, integral to the distribution of fluids and other electrolytes. Chloride ions act as a buffering agent in the lungs and tissues. Normal saline is widely used intravenously and topically (e.g. for cleaning wounds, nasal and ocular irrigation).

Therefore, a benchmark control substance of Normal Saline should be considered, unless a suitable alternative has been recommended by the manufacturer of the synthetic condom.

Polydimethylsiloxane (viscosity 100 to 300 × 10^{-6} m^2/s) is widely used for lubricating both natural rubber latex and synthetic condoms. It is known to have a small reversible effect on the physical properties of natural rubber. It may also be a suitable negative or benchmark control.

It is the responsibility of the laboratory doing the test to ensure that the negative or benchmark control used does not have an excessively deleterious effects on the condom. This may be done through thorough investigation of the published properties and compatibilities of the condom material, and/or physical comparison testing of condoms which have been wet with the proposed negative or benchmark control and those that have not.

5 Apparatus

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 head 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, conforming to 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 23409:2011, 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 Test condoms, conforming to ISO 23409, to which the test substance is applied. The condoms should be smooth and parallel-sided.

6.2 Negative control substance or benchmark substance, as discussed in Clause 4.

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

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

6.5 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 Where documented information is available to indicate that two or more condom products from different manufacturers are made with essentially identical specifications, raw materials and manufacturing processes, then one product may be used as representative of all such products. In that case, the test result can be applied to all condom products in such a group

Similarly, if one manufacturer produces a range of synthetic condom products with essentially identical raw materials and manufacturing processes, then the most vulnerable of the products may be identified through a risk analysis, and that product may be used to represent all the products in the range for the purpose of compatibility.

If the condom products cannot be grouped in this way, then the compatibility testing shall be done for each condom-test substance combination.

7.1.2 Each variant of condom should be supplied lubricated, from a single finished lot.

7.1.3 All condoms should meet the requirements of ISO 23409.

7.1.4 The data referred to in ISO 23409:2011, 17.1 should be obtained.

7.1.5 It is acceptable to purchase condoms from retail outlets or wholesalers.

7.2 Condom sample groups

7.2.1 Each of the variants of condoms should be randomised then divided into two groups and tested for physical properties in the following order.

a) Negative or benchmark control group: Condoms are tested according to 8.3 and 8.4, but the tensile samples/condoms are to be lubricated with the negative control or benchmark substance instead of the test substance. All other handling and testing of the control tensile samples/condoms should be exactly the same as for the test substance group. Ensure that 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.

7.3 Sample size

The recommended sample size for tensile testing and for inflation testing is not 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 (not exceeding 10 ml) of distilled water (or suitable solvent that does not have a deleterious effect on the condom properties) 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 (not exceeding 2 ml) of distilled water (or suitable solvent that does not have a deleterious effect on the condom properties) at a temperature of up to 45 °C prior to application.

8 Procedure

8.1 General

The negative or benchmark control test is performed first, and is 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.

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

8.2 Negative or benchmark control testing

For both inflation and tensile testing, a control test shall be conducted immediately before using the test substance. For this control testing, the negative control or benchmark substance 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 to be lubricated with the negative control or benchmark substance instead of the test substance. 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.

A suitable negative control or benchmark control substance shall be identified by the testing laboratory, preferably in consultation with the manufacturer of the condoms. Otherwise, the laboratory shall conduct its own investigations, through literature searches or through laboratory testing, to find a suitable substance. The choice of substance is discussed in Clause 4.

8.3 Inflation testing

For each of the product groups, mount not less than 30 samples on suitable cylindrical mounts. The mounts should be marked with a line indicating 150 mm from the hemispherical top. If the mounts 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 mount. 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 up to 10 ml of distilled water (or suitable solvent that does not have a deleterious effect on the condom properties) 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 mount 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 clean 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

Repeat the process until all condoms have been tested.

Record the number of samples, the type of test substance or control substance applied, and the burst volume and pressure as required in ISO 23409.

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 sample, 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 up to 2 ml of distilled water (or suitable solvent that does not have a deleterious effect on the condom properties) 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.

Tensile testing is conducted in accordance with Annex A.

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

Positive control testing can be useful in the following circumstances:

a) method verification;

b) technician training.

Ideally, a positive control substance should be:

1) known to cause a drop of at least 20 % in at least one of the physical properties being measured;

2) of a type that could reasonably be applied to the condom by a user;

3) safe to handle in the laboratory.

For some base materials, it may be impossible to find a suitable positive control substance. In these cases, some of the functions of positive control testing may be achieved by doing similar tests on latex condoms, using negative and positive control substances suitable for them.

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 the negative control or benchmark substance 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 following steps should be followed to determine the compatibility of a particular lubricant with a particular synthetic condom brand, or, where possible, a particular synthetic condom material.

a) Determine the mean and standard deviation for each combination of condom type and test substance including the negative 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.

c) For each property, calculate the 95 % two-sided confidence interval for the percentage ratios determined in step b). The procedures for doing this calculation are given in Annex B.

d) Assess the statistical and practical implications of the percentage ratios determined in steps c) and d) 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 overlaps 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, it 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.

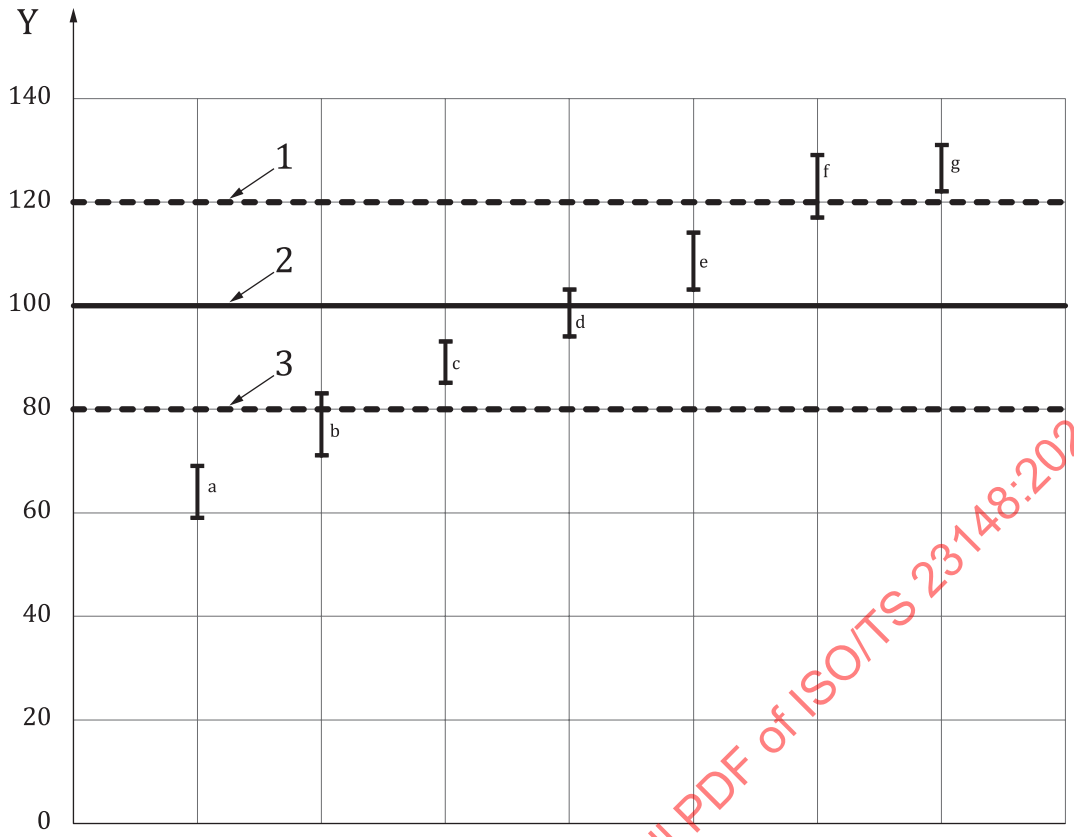
3) If the 95 % confidence interval for the percentage ratio includes 80 % or 120 % then the results are inconclusive. It might be possible to reduce the size of the 95 % confidence intervals by repeating the tests using larger sample sizes and so reach a conclusion based on a) or b). If the mean values 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 might show that the condom and test substance do have adequate compatibility.

Figure 1 shows examples 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 the synthetic condoms under test if the ratios of the physical properties at break comply with compatibility requirements of this clause.

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.



Key

Y 95 % confidence intervals for ratio of treated condom/control condom (%)
1 1,2
2 1
3 0,8
a Not compatible.
b Inconclusive.
c Compatible - Statistically significant decrease.
d Compatible - No statistically significant change.
e Compatible - Statistically significant increase.
f Inconclusive.
g Not compatible.

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 and elongation 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 benchmark or negative control substance used.

Report the ratio (expressed as a percentage to the nearest whole number) of the mean values of each parameter, after exposure to that with exposure to the control, 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

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.6 Calculation of tensile strength

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):

$$\sigma = \frac{F_b}{2wt} \quad \text{(A.3)}$$

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.

Annex B
(informative)

Determination of the confidence interval for the ratio of two means

B.1 General

Two methods of calculating the standard error and the confidence intervals for the ratio of the properties of the condoms exposed to the test substance and the control condoms are given in this annex. Both methods rely on the assumption that the measured properties are normally distributed and that the treated and control condoms are not paired or correlated.

B.2 Calculation of the ratio

The ratio (quotient), Q, of the mean result for the treated condom, R_t, divided by the mean result for the control condom, R_c, is given by Formula (B.1):

$$Q = \frac{R_t}{R_c} \tag{B.1}$$

Q can be expressed as a percentage by multiplying R_t/R_c by 100.

B.3 Calculation of approximate standard errors and confidence intervals

The standard error of Q (SE_Q) is given approximately by Formula (B.2):

$$SE_Q = \sqrt{\frac{SEM_{R_t}^2}{R_t^2} + \frac{SEM_{R_c}^2}{R_c^2}} \tag{B.2}$$

where SEM_{Rt} and SEM_{Rc} are the standard errors of the means of the treated and control condoms, respectively. These are calculated from Formulae (B.3) and (B.4):

$$SEM_{R_t} = \sqrt{\frac{SD_{R_t}^2}{n_{R_t}}} \tag{B.3}$$

and

$$SEM_{R_c} = \sqrt{\frac{SD_{R_c}^2}{n_{R_c}}} \tag{B.4}$$

where

SD_{R_t} is the standard deviation of R_t;

SD_{R_c} is the standard deviation of R_c;

n_{R_t} is the number of treated samples tested;

n_{R_c} is the number of control samples tested.

The standard error of Q can be expressed as a percentage is simply obtained by multiplying SE_Q by 100.