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Additional lubricants for male synthetic condoms — Effect on condom strength

Lubrifiants supplémentaires pour les préservatifs masculins synthétiques — Effet sur la résistance du préservatif

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Foreword

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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 flash off. 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 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.

Additional lubricants for male synthetic condoms — Effect on condom strength

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 23409:2011, *Male condoms — Requirements and test methods for condoms made from synthetic materials*

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

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 (3.4) 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 (3.5) which is known to cause deterioration in the physical properties of the condom being evaluated

3.5
test substance
personal lubricant (3.3), *topical medicine* (3.6) or other material which is being tested for compatibility with condoms

3.6
topical medicine
medicine intended to be used 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 hours 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 raw materials may be used. In many cases, therefore, there will only be one or two products from each raw 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 raw 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 raw 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 below are in accordancewith 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 will be a suitable negative control for synthetic condoms, but there could 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 needs to be small enough to leave the condom fit for purpose in use. Condoms that conform to ISO 23409 should 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 may 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.

The purpose of the positive control is to establish that the manipulation of condoms as outlined in the test methods will cause significant deterioration in the presence of a substance, thus showing that the test actually distinguishes between a deleterious substance and one that is not.

It is not necessary to show that a deleterious substance will adversely affect the particular condom material being evaluated. While it is preferable to demonstrate positive control testing on the condoms for which compatibility is to be established, it is also possible to demonstrate it on other products. This can, for example, mean showing that the handling and oven conditioning of natural latex condoms treated with mineral oil results in significantly lower physical properties than with distilled water.

5 Apparatus

5.1 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.

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

5.3 Ring-cutting die, mechanical press, and replaceable cutting surface, for cutting ring specimens from condoms, in accordance with Annex A.

5.4 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.

5.5 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.

5.6 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.

5.7 Inflation tester, suitable for testing condoms in accordance with ISO 23409:2011, Annex H.

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

5.9 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, in accordance with ISO 23409, to which the test substance is applied. The condoms should be smooth and parallel-sided.

6.2 Positive control substance, for positive control testing. This substance should be chosen on the basis that it is known to have a significant adverse effect on the physical properties of the material. Such positive controls should be of a type that can reasonably be applied by the user to a condom. If such a product is not available, then the positive control testing should demonstrate that the test as carried out produces an adverse effect on the physical properties of a natural latex condom, using a positive control suitable for natural rubber latex such as mineral oil.

6.3 Additional positive control, if applicable, for testing transient deleterious effects. These are substances like Cyclomethicone D5, which could initially cause weakness in some materials, but then evaporate rapidly from the surface of the condoms after application.

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

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 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) Control group: Condoms are tested according to 8.3 and 8.4, but the tensile samples/condoms are lubricated with the negative control or benchmark 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.

7.2.2 Where possible, 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) can be tested, either instead of, or after, the test substance group. Otherwise, the method can be validated using natural rubber latex condoms and mineral oil, compared with distilled water on the same lot of condoms.

7.3 Sample size

The recommended sample size for tensile 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