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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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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:

— correction of Formula (B.4).

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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.

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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

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