



Designation: D7661 – 18

Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms¹

This standard is issued under the fixed designation D7661; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers procedures used to detect a shift in physical properties of natural rubber latex (NRL) condoms after immersion in a personal lubricant. “Personal lubricants” are lubricants such as liquids or gels that are applied by the consumer at the time of condom use.

1.2 This test method does not attempt to address compatibility of lubricants applied to a condom at the time of manufacture (“manufacturer lubricants”). It shall be the responsibility of the condom manufacturer to verify the long-term stability (shelf life) of any manufacturer lubricant that is packaged within the individual condom wrapper. Other regulatory requirements may apply.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

D3492 Specification for Rubber Contraceptives (Male Condoms)

¹ This test method is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Summary of Test Method

3.1 This test method measures the change in tensile and airburst properties, specifically force at break, percent elongation at break, airburst pressure, and airburst volume, of NRL condoms and condom rings after 60 min of immersion in a liquid or gel lubricant. Condoms (up to the open end) and rings cut from condoms are immersed in personal lubricant, heated to body temperature, cleaned of excess lubricant, and tested for both tensile and airburst properties. Those properties are then compared to control condoms and rings that are subjected to the same procedures without adding lubricant. For comparison purposes, baseline testing is also performed on condoms directly from their packages. A final group exposed to mineral oil is also included to validate the laboratory's test technique.

3.2 A flow chart of the lubricant compatibility tensile test component is shown in **Fig. 1**. A flow chart of the lubricant compatibility airburst test component is shown in **Fig. 2**. Each step of the process shall be performed immediately after the conclusion of the previous step.

4. Significance and Use

4.1 Weakening of natural rubber latex is known to occur after contact with certain lubricants, particularly petroleum-based products.^{3,4} This procedure was developed as a screening method for lubricant manufacturers to determine whether or not a particular personal lubricant has a significant effect on the tensile and airburst properties of an NRL condom.

4.2 This test method is designed for use on NRL condoms that meet the criteria of Specification **D3492** and can: (1) have a ring specimen cut in compliance with Appendix X1 of

³ White, N., Taylor, K., Lyszkowski, A., Tullett, J., and Morris, C., Dangers of lubricants used with condoms, *Nature*, 1988, Sep 1;335(6185):19.

⁴ Voeller, B., Coulson, A., Bernstein, G., and Nakamura, R., Mineral oil lubricants cause rapid deterioration of latex condoms, *Contraception*, 1989, Jan;39(1):95-102.