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.

Designation: D5712 – 15 (Reapproved 2020)

Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method[1]

This standard is issued under the fixed designation D5712; 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 an analytical test for determining the amount of total aqueous extractable protein associated with NR, latex, and elastomeric products. Water soluble proteins are extracted in a buffer solution and then precipitated to concentrate them and also to separate them from water soluble substances that may interfere with the determination. The extracted protein is redissolved and quantified colorimetrically by the modified Lowry method using a protein standard.

1.2 For the purpose of this test method, the range of protein measurement will be based on the limit of detection and quantitation and recorded in micrograms per dm^2 test specimen.

1.3 The test method is designed to be accurate and compatible with the industrial environment.

1.4 Steps are included in this test method to minimize the effects of interfering substances.

1.5 It is recognized that other methods for the analysis of leachable proteins exist and these may be used for routine quality control purposes provided they have been validated and a correlation established against the reference method specified by this test method.

1.6 This test method has not been validated for use with lubricated products such as condoms. Condoms with different lubricants as typically marketed, have not been tested in an ASTM ILS to determine if, and if so to what degree, the lubricant interferes with the assay.

1.7 *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.*

1.8 *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]

D3577 Specification for Rubber Surgical Gloves

D3578 Specification for Rubber Examination Gloves

D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries

3. Terminology

3.1 *Definitions:*

3.1.1 *background*—the absorbance measurement of the Lowry assay in the absence of the protein analyte.

3.1.2 *calibration*—the standardization of an instrument setting.

3.1.3 *calibration solution*—the standard solution used to routinely and reproducibly calibrate a measuring instrument.

3.1.4 *concentration range*—the recommended analyte concentration range in µg/mL that produces an absorbance measurement of 0.01 to 1.5 units at 600 to 750 nm.

3.1.5 *dilution factor (F)*—the ratio of the volume NaOH in millilitres used to redissolve the test specimen extract to volume NaOH in millilitres used to redissolve the standard ovalbumin proteins. For example, if protein in a 1-mL test extract is acid precipitated and redissolved in 0.25 mL, and the ovalbumin protein standards are also redissolved in 0.25 mL, then the dilution factor ratio of the test extract to that of the calibration curve would equal one.

[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.

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