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: D7427 – 16 (Reapproved 2021)

Standard Test Method for Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Hevea Natural Rubber and Its Products Derived from Latex[1]

This standard is issued under the fixed designation D7427; 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 immunological method known as an immunoenzymetric assay to quantify the amount of 4 principal *Hevea brasiliensis [Hev b]* allergenic proteins [Hev b 1, Hev b 3, Hev b 5 and Hev b 6.02] in Hevea natural rubber and its products[2] derived from latex using monoclonal antibodies specific for epitopes on these proteins. Since these assays quantify the levels of only 4 of the known 14 officially acknowledged allergens potentially present in Hevea natural rubber latex containing products, the sum of the four allergen levels shall be viewed as an indicator of the allergen burden and not as a measure of the total allergen content that can be released from the product.

1.2 For the purpose of this test method, the range of allergenic protein will be measured in terms of nanogram to microgram quantities per gram or unit surface area of a Hevea natural rubber containing product.

1.3 The test method is not designed to evaluate the potential of Hevea natural rubber containing materials to induce or elicit Type I (IgE-mediated) hypersensitivity reactions.

1.4 This test method should be used under controlled laboratory conditions to detect and quantify the level of 4 allergenic proteins found in Hevea natural rubber containing products. It should not be used to describe, appraise or assess the hazard or risk of these Hevea natural rubber containing materials or products under actual in use conditions.

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

1.6 *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.*

1.7 *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:*[3]

D1193 Specification for Reagent Water

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

D4678 Practice for Rubber—Preparation, Testing, Acceptance, Documentation, and Use of Reference Materials

D5712 Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

D6499 Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products

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

3. Terminology

3.1 *Definitions:*

3.1.1 *accepted reference value (ARV)*—value that serves as an agreed upon reference for comparison and which is derived as *(1)* a theoretical or established value, based on scientific principles, *(2)* an assigned or certified value, based on experimental work of some national or international organization, or

[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] This procedure has not been validated for condoms, particularly lubricated condoms, which could contain surfactants or other ingredients that could interfere with the assay.

[3] 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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