



Designation: F719 – 20^{ε1}

Standard Practice for Testing Materials in Rabbits for Primary Skin Irritation¹

This standard is issued under the fixed designation F719; 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

^{ε1} NOTE—Editorial correction was made to 8.1 in November 2020.

1. Scope

1.1 This practice covers a procedure by which the irritancy of a material may be assessed through contact with abraded and intact skin of rabbits.

1.2 The results of this practice depend upon the effectiveness with which contact between the skin and the test material is established and maintained. Because of the operator technique included in performing this test, it is important that the test be performed by personnel with appropriate training.

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 may involve hazardous materials, operations, and equipment. 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

F619 Practice for Extraction of Materials Used in Medical Devices

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

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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.

3. Summary of Practice

3.1 Exposure of skin to the test material is accomplished by means of a patch test technique employing two intact and two abraded sites on the back of each of three albino rabbits per test article. The skin is clipped free of hair one day prior to testing. The test substance is applied using 0.5 mL for liquids, 0.5 g for solids or semisolids, and a 2.5 by 2.5-cm square patch for films. After application, each test site is covered with a 2.5 by 2.5-cm gauze flat, and the entire trunk is occluded with a polyethylene sleeve. After 24 h, the sleeve, flat, and test material are removed, and test sites are evaluated for erythema and edema.

4. Significance and Use

4.1 Materials that are to be in contact with the skin should not cause irritation to the skin. Since it is probably the substances leached from a material that cause the irritation, this practice provides for direct material-skin contact testing or for skin exposure to the liquid extract of the test material. The rationale for this rabbit test is that it is a comparatively quick and sensitive method which, through use over the years, has become a generally accepted method. Additionally, the albino rabbit allows for easy visualization of erythema and edema, which are the cardinal signs of skin irritation.

5. Materials and Manufacture

5.1 *Young New Zealand Albino Rabbits*, Healthy young adult albino rabbits of either sex, weighing not less than 2 kg, shall be used. Animal care shall be in accordance with the "Guide for Care and Use of Laboratory Animals";³

5.2 *Gauze Flats*, 2.5 by 2.5-cm;

5.3 *Polyethylene Sleeves*, extra clear;

5.4 *Adhesive Tape*, 1/2-in. width.

6. Test Specimen

6.1 The test specimen may be one of three forms:

6.1.1 Test 0.5 mL of liquids, saline, or vegetable oil extract liquids obtained in accordance with Practice F619.

³ National Research Council, "Guide for the Care and Use of Laboratory Animals," Washington, DC, *National Academy Press*, 2011.