Designation: F392/F392M − 21

Standard Practice for Conditioning Flexible Barrier Materials for Flex Durability[1]

This standard is issued under the fixed designation F392/F392M; 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 practice covers conditioning of flexible barrier materials for the determination of flex resistance. Subsequent testing can be performed to determine the effects of flexing on material properties. These tests are beyond the scope of this practice.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.3 *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.*

1.4 *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]

E171 Practice for Conditioning and Testing Flexible Barrier Packaging

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

3. Terminology

3.1 *pinhole, n*—a small opening of non-specific shape or dimension that passes completely through all layers of a flexible material.

3.1.1 *Discussion*—The use of the term "pin" provides the relative size reference as in a small hole made with or as if with a pin.

4. Summary of Practice

4.1 Specimens of flexible materials are flexed at standard atmospheric conditions defined in Practice E171, unless otherwise specified. Flexing conditions, number of cycles, and severity of flexing strokes vary with the type of material structure being tested. Except for condition E, the flexing condition consists of a twisting motion followed, in conditions A to D, by a horizontal motion, thus, repeatedly twisting and crushing the film. The frequency is at a rate of 45 cycles per minute (cpm).

4.2 Flex failure is determined by measuring the effect of the tested flex conditioning on the barrier and/or mechanical performance of the structure. The property to be evaluated determines the appropriate conditioning level.

4.3 The various flex conditioning levels are summarized as follows:

4.3.1 *Condition A*—Full flex for 1 h (that is, 2700 cycles).

4.3.2 *Condition B*—Full flex for 20 min (that is, 900 cycles).

4.3.3 *Condition C*—Full flex for 6 min (that is, 270 cycles).

4.3.4 *Condition D*—Full flex for 20 cycles.

4.3.5 *Condition E*—Partial flex for 20 cycles.

5. Significance and Use

5.1 This practice is valuable in determining the resistance of flexible packaging materials to flex-formed pinhole failures. Conditioning levels A, B, or C are typically used. Reference Practice E171 and Guide F2097.

5.2 Conditioning D and E are typically used for determining the effect of flexing on barrier properties transmission rates related to gas and/or moisture.

5.3 This practice does not measure or condition materials for abrasion related to flex failure.

5.4 Failures in the integrity of one or more of the plies of a multi-ply structure may require alternative testing. Supplementary permeation testing using gas or water vapor can be used in conjunction with the flex test to measure the loss of ply integrity. Other test methods may be used after flexing for

[1] This practice is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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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.

assessment of presence of pinholes. For a list of test methods, refer to Guide F2097.

5.4.1 The various conditions described in this practice are to prevent evaluating a material structure with an outcome of too many holes to effectively count (normally greater than 50), or too few to be significant (normally less than five per sample). Material structure, testing basis, and a mutual agreement with specified objectives are to be considered in the selection of conditioning level for testing.

6. Apparatus

6.1 *Flex Tester,* is designed in accordance with Section 9. This apparatus shall consist essentially of a 90 ± 1-mm [3.5-in.] diameter stationary mandrel and a 90 ± 1-mm [3.5-in.] diameter movable mandrel spaced at a distance of 180 ± 2 mm [7 in.] apart from face-to-face at the starting position (that is, maximum distance) of the stroke. Mandrels shall contain vents to prevent pressurization of samples. The specimen supporting shoulders on the mandrels shall be 13 ± 1 mm [0.5 in.] wide. The motion of the movable mandrel is controlled by an attached grooved shaft. For the full or maximum stroke, the groove is designed to give a twisting motion of 440 ± 4° in the first 90 mm [3.5 in.] of the stroke of the movable mandrel, followed by a straight horizontal motion of 65 mm [2.5 in.], so that at the closed position the mandrels are 25 ± 1 mm [1 in.] apart. The motion of the movable mandrel is reciprocal with a full cycle consisting of the forward and return strokes.

6.1.1 Fig. 1 shows the planar evolution of the helical groove in the driven shaft to administer the required 440° (37° helix angle) twisting motion and the straight horizontal motion.

6.1.2 For the partial flex, Condition E, the movable head is set to travel only 80 mm [3.25 in.] of the 180-mm [7-in.] spacing. Only approximately 90 % of the twisting stroke is utilized resulting in a twisting motion of 400°.

6.2 *Tape,* flexible, double-sided, pressure-sensitive, not more than 13 mm [0.5 in.] wide.

6.3 *Template,* for cutting 200 mm by 280 mm ± 2-mm [8 by 11-in.] samples.

7. Test Specimens—All Conditions

7.1 Cut the samples into 200 mm by 280-mm [8 in. by 11-in.] flat sheets with the 200-mm [8-in.] dimension in the machine or transverse/cross direction. This will also be the direction of the flex-tester motion axis.

7.2 Flex condition specimens in their machine direction and the same amount in their transverse/cross direction. In addition, it is recommended to collect an equal number of control

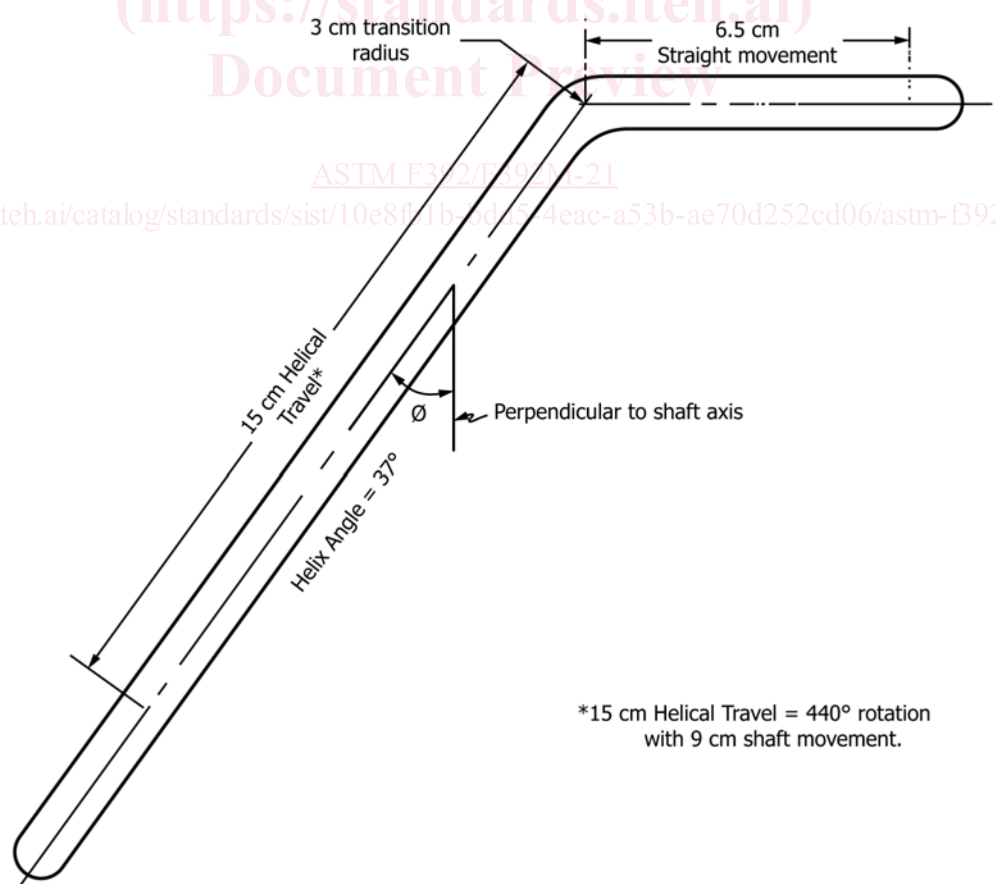

FIG. 1 Planar Evolution of Gelbo Shaft Helical Groove 30.70-mm [1.20-in.] Diameter Shaft