



Designation: D4754 – 18

Standard Test Method for Two-Sided Liquid Extraction of Plastic Materials Using FDA Migration Cell¹

This standard is issued under the fixed designation D4754; 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.

1. Scope*

1.1 This test method covers the use of the FDA migration cell in the extraction of components and permits quantitation of individual migrants from plastic materials by suitable extracting liquids, including liquid foods and food-stimulating solvents.

1.2 This test method provides a two-sided, liquid extraction test for plastic materials that can be formed into film, sheet, or disks.

1.3 This test method has been applied to a variety of migrant/polymer systems in contact with numerous foods and food simulants.² Though most of the migrants examined were radiolabeled, the use of the FDA cell has been validated for migration studies of unlabeled styrene from polystyrene.³

1.4 This test method has been shown to yield reproducible results under the conditions for migration tests requested by the FDA. However, if the data is to be submitted to the FDA, it is suggested that their guidelines be consulted.

1.5 Because it employs two-sided extraction, this test method may not be suitable for multi-layered plastics intended for single-sided food contact use.

1.6 The size of the FDA migration cell as described may preclude its use in determining total nonvolatile extractives in some cases.

NOTE 1—For more information, see Practice D1898, the AOAC Methods of Analysis on Flexible Barrier Materials Exposed for Extraction, and the Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations, December 2007.

¹ This test method is under the jurisdiction of ASTM Committee D20 on Plastics and is the direct responsibility of Subcommittee D20.70 on Analytical Methods.

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² “A Study of Indirect Food Additive Migration,” Arthur D. Little, Inc., FDA Contract No. 223-77-2360.

³ Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:D20-1141.

1.7 Analytical procedures must be available to quantitate the migrant(s) generated by this test method.

1.8 The values stated in SI units are to be regarded as the standard.

1.9 *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. Specific hazards statements are given in Section 8.*

NOTE 2—There is no known ISO equivalent to this test method.

1.10 *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:*⁴

D883 Terminology Relating to Plastics

D1898 Practice for Sampling of Plastics (Withdrawn 1998)⁵

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

IEEE/ASTM SI 10 Standard for Use of the International System of Units (SI): The Modernized Metric System

2.2 *Association of Official Analytical Chemists (AOAC) Methods of Analysis:*

Flexible Barrier Materials Exposed for Extraction⁶

⁴ 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.

⁵ The last approved version of this historical standard is referenced on www.astm.org.

⁶ Available through the Association of Official Analytical Chemists, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877-2417 USA.

*A Summary of Changes section appears at the end of this standard