Designation: D3810 – 97 (Reapproved 2007)

Standard Test Method for Minimum Application Torque of Type IA Child-Resistant Closures[1]

This standard is issued under the fixed designation D3810; 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 the determination of or the recommendation for minimum application torque that results in a fully degraded removal torque that is at a level greater than the maximum expected reverse-ratchet torque for a Type IA child-resistant closure. (See Classification D3475).

1.2 This test method provides a procedure that will assure the maintenance of the respective child-resistant properties of Type IA child-resistant closures.

1.3 A major limitation to the determination of minimum application torque of Type IA child-resistant closures is because many cappers lack the capability for measuring closure application torques; therefore, minimal recommendations derived from this method are, of necessity, defined in terms of the immediate removal torques.

1.4 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D3198 Test Method for Application and Removal Torque of Threaded or Lug-Style Closures

D3472 Test Method for Reverse-Ratchet Torque of Type IA Child-Resistant Closures

D3474 Practice for Calibration and Use of Torque Meters Used in Packaging Applications

D3475 Classification of Child-Resistant Packages

2.2 *Other Standards:*

16 CFR 1700 Title 16—Commercial Practices, Chapter II—CPSC, Subchapter E, Poison Prevention Packaging Act of 1970 Regulations, Part 1700—Poison Prevention Packaging[3]

ISO Bulletin 2233 Packaging—Complete, Filled, Transport Packages—Part 2: Conditioning for Testing[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *Type IA child-resistant closure*—a reclosable continuous thread closure requiring a random push-down force while turning to remove from the container. No orientation of the push-down force is necessary.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *application torque*—the moment of a force or the system of forces tending to cause rotation of an appropriate closure over the neck finish of an appropriate container, causing the closure to be applied and secured to the container.

3.2.2 *removal torque*—the moment of a force or the system of forces tending to cause rotation of an appropriate closure in a direction opposite to that of application causing the closure to be unsecured from its position on the neck finish of an appropriate container.

3.2.3 *reverse-ratchet torque*—the moment of a force or the system of forces tending to cause rotation of the outer shell over the inner shell of a Type IA child-resistant closure. The rotation is in a direction opposite to that for closure application.

3.2.4 *degraded removal torque*—that removal torque found, after a suitable period of storage of the package under controlled conditions of temperature and relative humidity, when the liner (or cap, if there is no liner) is at a completely relaxed state and when no significant change occurs in the removal torque after this period of storage.

[1] This test method is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical, Medical, and Child Resistant Packaging.

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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] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

4. Summary of Test Method

4.1 Representative samples of Type IA child-resistant closures and appropriate containers are preconditioned in a controlled environment of temperature and relative humidity.

4.2 Representative samples of Type IA child-resistant closures are then applied to appropriate containers using a torque-measuring device.

4.3 Reverse-ratchet torque ranges are determined by using Test Method D3472.

4.4 Application torque level ranges are evaluated by using Test Method D3198.

4.5 Tests are continued over an appropriate period of time sufficient to demonstrate no significant change in closure removal torque levels.

5. Significance and Use

5.1 This test method may be used to:

5.2 Compare the functioning of two or more kinds of Type IA closures.

5.3 Determine or aid in the recommendations for minimum immediate removal torque or minimum application torque for the proper securing of Type IA child-resistant closures after evaluation of the torque degradation characteristics of the closure-container system.

5.4 Compare immediate removal torque to fully degraded, with long-term storage, removal torque for a given closure-container system.

5.5 Provide for the evaluation of one aspect of child-resistant closure continuous functioning by projected reverse-ratchet abuse.

5.6 Compare application torque retentions of given Type IA closures following a change in lining material, closure material, container type, or any other change from the closure-container system initially evaluated.

5.7 Assure by determining reverse-ratchet torques and removal torques, that the given Type IA child-resistant closure is continuing to function as it did during child and adult protocol (16 CFR 1700.20).

6. Apparatus

6.1 *Torque Meter,* with a scale that will read with the maximum point reading accuracy within the torque range expected to be measured.

NOTE 1—A digital or automated torque instrument, if used, will have an appropriate design and scale capacity for the container/closure system to be evaluated. Torque results will be available in either electronic display or printout formats.

7. Sampling, Test Specimens, and Test Unit

7.1 Select sufficient closure-container combinations to provide a minimum of five specimens for each time interval and each torque level chosen as a data point.

7.1.1 Data points should be chosen to encompass a minimum duration of four weeks to assure no further significant change in torque degradation.

NOTE 2—While the greater portion of the torque change may be expected to occur within the initial three days after closure application, the torque may continue to change for some additional time.

7.1.2 Data points should include immediate testing, one day, one week, two weeks, three weeks, and four weeks.

7.1.3 Select unused closures, complete with liners if appropriate, and unused containers, with the correct corresponding size finish, that are within specifications.

8. Calibration

8.1 Calculate the torque meter in accordance with Practice D3474.

9. Conditioning

9.1 Control the relative humidity and temperature conditions in such a way that the data may be reasonably comparable when repetitive testing of closure-container combinations for removal torque is intended. The atmosphere conditions in Table 1 may be used when special conditioning is applicable. Other atmosphere conditions may also be used as appropriate.

NOTE 3—Closure application and removal torque levels may be influenced by such variables as time, temperature, relative humidity, and conditioning of the closures and containers prior to testing and by temperature and relative humidity during storage and at the time of testing.

9.2 Precondition the components separately in a controlled environment of temperature and relative humidity a minimum of 48 h prior to their being combined into closure-container systems to be evaluated. Do not stack the components to assure an adequate circulation of air around them.

9.2.1 For temperatures that are considered to be extreme, a tolerance of ±3°C is recommended. For temperatures that are not considered to be extreme, a tolerance of ±2°C is recommended. For relative humidity, a tolerance of ±2 % relative humidity is generally expected to be the total variation in well-designed conditioning modules.

10. Procedure

10.1 Select a minimum of three application torque levels for testing.

10.1.1 A suggested range for immediate removal torques for the various test levels is:

(1) 8 to 10 T.I.P. (torque inch pounds-force) (0.90 to 1.13 N·m)
(2) 14 to 16 T.I.P. (torque inch pounds-force) (1.58 to 1.31 N·m)
(3) 19 to 21 T.I.P. (torque inch pounds-force) (2.15 to 2.37 N·m)
(4) 24 to 26 T.I.P. (torque inch pounds-force) (2.71 to 2.94 N·m)

10.2 Apply the closures to the appropriate containers within 2 h of the components' removal from the controlled environment.

TABLE 1 Special Atmospheres

Environment	Temperature,° C (°F)	Relative Humidity, %
Cryogenic	−55 ± 3 (−67 ± 6)	...
Frozen food storage	−18 ± 2 (0 ± 4)	...
Refrigerated storage	5 ± 2 (41 ± 4)	85 ± 5
Temperature high humidity	20 ± 2 (68 ± 4)	85 ± 5
Tropical	40 ± 2 (104 ± 6)	85 ± 5
Desert	60 ± 3 (140 ± 6)	15 ± 2

10.2.1 Prepare the closure-container combinations as near to the normal manufacturing conditions as possible to allow for variables, such as containers and closures subjected to hot fill, containers wet before filling and at the point of capping, and product on the container threads and sealing surfaces of the container finish.

10.3 Hand apply all closures to the appropriate containers by using a bench-style torque meter and a relatively slow, uniform rate of application.

NOTE 4—It is recommended that one operator apply all closures in any given test of a closure-container combination to reduce possible operator inconsistencies.

10.4 Apply a minimum of five closures to the appropriate containers for each application torque level selected. Immediately remove these closures with the aid of a bench-style torque meter by using a relatively slow, uniform rate of removal. Record these removal torques.

NOTE 5—It is recommended that one operator remove all closures in any given test of a closure-container combination to reduce possible operator inconsistencies. It is further recommended that one operator both apply and remove all closures in any one test of a closure-container combination.

10.5 Apply the balance of the closures to the appropriate containers by repeating 10.3, using a minimum of five closures for each of the remaining application torque levels, storage periods, and conditions selected. Remove the closures, when specified, as described in 10.4.

10.6 Determine that application torque level, or immediate removal torque level, when the removal torque shows no further significant degradation. This will provide a fully degraded removal torque at a level greater than the maximum expected closure reverse-ratchet torque.

10.7 After the minimum application torque levels or minimum immediate removal torque levels are determined, packaging line torque control levels may be established based on packaging line torque capabilities.

10.8 When testing is being conducted to recommend removal torque levels or production line application torque levels, projected abuse of the closure reverse-ratchet feature may be evaluated. Maximum abuse of the reverse-ratchet feature implied by the child and adult protocol (16 CFR 1700.20) would be continued rotation of the closure outer shell in a direction opposite to the application direction for a 10-min period. If this feature is to be tested, this continued rotation should be maintained at a rate normally expected from a child who might manipulate the closure in this manner.

11. Report

11.1 The report shall include the following:

11.2 Thread finish and other designation of the closure.

11.3 Materials of construction of the closure, including any liner and liner coating(s).

11.4 Finish and materials of construction of the container and mold release or annealing agents, where applicable.

11.5 Preconditioning time, temperature range, and relative humidity range of the components.

11.6 Storage time, temperature range, and relative humidity range in the room where the components will be combined into the packages to be evaluated.

11.7 Temperature range and relative humidity range in the room during the period of testing.

11.8 Description of all simulated packaging conditions under which the closures and containers are combined, if applicable.

11.9 Description of torque measuring device used.

11.10 Number of replicates.

11.11 Mean, range, and standard deviation of torque values for all levels, conditions, and time interval data points expressed in torque inch pounds-force and newton metres.

11.12 Statement that this test was done in accordance with Test Method D3810 or a note describing any exceptions to or deviations from this test method.

12. Precision and Bias

12.1 *Precision*—The repeatability standard deviation of the removal torque is about 0.95 in.- lb or 7 % of the average. This is based on limited data of one package from two laboratories. Other packages may have different repeatability values. The reproducibility of this test method is being determined.

12.2 *Bias*—No justifiable statement can be made on the bias of this test method since a true value cannot be established by an accepted referee method.

13. Keywords

13.1 application torque; degraded removal torque; removal torque; reverse-ratchet torque; Type IA child-resistant closures