

16. If more adults in a sex or age group are tested than are necessary to determine SAUE, the last person(s) tested shall be eliminated from that group.

(4) *Younger-adult panel.* (i) One hundred adults, age 18 to 45 inclusive, with no overt physical or mental handicaps, and 70% of whom are female, shall comprise the test panel for younger adults. Not more than 35% of adults shall be obtained or tested at any one site. No individual tester shall administer the test to more than 35% of the adults tested. The adults shall be tested individually, rather than in groups of two or more. The adults shall receive only such printed instructions on how to open and properly resecure the special packaging as will appear on the package as it is delivered to the consumer. Five minutes shall be allowed to complete the opening and, if appropriate, the resealing process.

(ii) Records shall be kept of the number of adults unable to open and of the number of the other adults tested who fail to properly resecure the special packaging. The number of adults who successfully open the special packaging and then properly resecure the special packaging (if resealing is appropriate) is the percent of adult-use effectiveness of the special packaging. In the case of unit packaging, the percent of adult-use effectiveness shall be the number of adults who successfully open a single (unit) package.

4. Add a new § 1700.20(d), reading as follows.

§ 1700.20 Testing procedure for special packaging.

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(d) Recommendations. The following instructions and procedures, while not required, are used by the Commission's staff and are recommended for use where appropriate.

(1) *Report format for child test.*

A. Identification

1. Close-up color photograph(s) clearly identifying the package and showing the opening instructions on the closure.

2. Product name and the number of tablets or capsules in the package.

3. Product manufacturer.

4. Closure model (trade name—e.g., "KLIK & SNAP").

5. Closure size (e.g., 28 mm).

6. Closure manufacturer.

7. Closure material and color(s) (e.g., white polypropylene).

8. Closure liner material.

9. TAC seal material.

10. Opening instructions (quote exactly, e.g., "WHILE PUSHING, DOWN, TURN RIGHT"). Commas are used to separate words that are on different lines.

11. Symbols, numbers, and letters found inside the closure.

12. Package model.

13. Package material and color.

14. Net contents.

15. Symbols, numbers, and letters on the bottom of the package.

16. Other product identification, e.g., EPA Registration Number.

B. Procedures

1. Describe all procedures for preparing the test packages.

2. Describe the testing procedures.

3. Describe all instructions given to the children.

4. Define an individual package failure.

C. Results

1. Openings in each 5-minute period and total openings for males and for females in each age group.

2. Opening methods (e.g., normal opening, teeth, etc.).

3. Mean opening times and standard deviation for each 5-minute test period.

4. The percentage of packages tested at each site as a percentage of total packages.

5. The percentage of packages tested by each tester as a percentage of total packages.

6. Child-resistant effectiveness for the first 5-minute period and for the total test period.

(2) *Standardized adult-resealing test instructions.* CPSC will use the adult-resealing test where an objective determination (e.g., visual or mechanical) that a package is properly resealed cannot be made. The adult-resealing test is performed as follows:

Adult-Resealing Procedure

1. After the adult participant in either the senior-adult test of 16 CFR 1700.20(a)(3) or the younger-adult test of 16 CFR 1700.20(a)(4) has resealed the package, or at the end of the test period (whichever comes first), the tester shall take the package and place it out of reach. The adult participant shall not be allowed to handle the package again.

2. The packages that have been opened and appear to be resealed by adults shall be tested by children according to the child-test procedures to determine if the packages have been properly resealed. The packages are given to the children without being opened or resealed again for any purpose.

3. Using the results of the adult tests and the tests of apparently-resealed packaging by children, the adult use effectiveness is calculated as follows:

a. *Adult use effectiveness.*

1. The number of adult opening and resealing failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-resealed packages, equals the total number of failures.

2. The total number of packages tested by adults (which is 100) minus the total number of failures equals the percent adult-use effectiveness.

(3) *Report format for adult-resealing test.*

A. Identification

1. Close-up color photograph(s) clearly identifying the package and showing the top of the closure.

2. Product name and the number of tablets or capsules in the package.

3. Product manufacturer.

4. Closure model (trade name).

5. Closure size (e.g., 28 mm).

6. Closure manufacturer.

7. Closure material and color(s) (e.g., white polypropylene)

8. Closure liner material.

9. Symbols, numbers, and letters found inside the closure.

10. TAC seal material.

11. Opening instructions (Quote exactly, e.g., "WHILE PUSHING, DOWN, TURN RIGHT"). Commas are used to separate words that are on different lines.

12. Package model.

13. Package material and color.

14. Net contents.

15. Symbols, numbers, and letters on the bottom of the package.

16. Other product identification, e.g., EPA Registration Number.

B. Procedures

1. Describe all procedures for preparing the test packages.

2. Describe the testing procedures in detail.

3. Describe all instructions given to participants.

4. Define an individual package failure and the procedures for determining a failure.

C. Results

Adult Test

1. Total packages opened and total packages resealed; packages opened by males and by females; and packages resealed by males and by females.

2. Mean opening times and standard deviation for total openings, total openings by females, and total openings by males.

3. Mean resealing times and standard deviation for total resealings, total resealings by females and total resealings by males.

4. The percentage of packages tested at each site as a percentage of total packages.

5. The percentage of packages tested by each tester as a percentage of total packages.

6. Methods of opening (e.g., normal opening, pried closure off, etc.)

Child Test

1. Openings in each 5-minute period, and total openings, for males and females in each age group.

2. Opening methods.

3. Mean opening times and standard deviation for each 5-minute test period.

4. The percentage of packages tested at each site as a percentage of total packages.

5. The percentage of packages tested by each tester as a percentage of total packages.

(4) *Consent forms.* The Commission uses the following consent forms for senior-adult testing reclosable and unit-dose packaging, respectively.

1. *Reclosable packages.*

[Testing Organization's Letterhead]

Child-Resistant Package Testing