Evaluation of

Secure Sack

as a poison prevention package for

DYMAPAK.

by

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April 24, 2017

DYMAPAK
PO Box 3332
New York, NY 10163

Attention: Steve Annunziato;

Below is Bitner Associates Final Report Secure Sack as a
Poison Protection Package.
Test units were evaluated using the Consumer Product Safety Commission Protocol and Standards. Study indicates Secure Sack fulfills requirements for Poison Prevention Package as per current Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Sincerely,
BITNER ASSOCIATES, Inc.

John Bitner
President

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I. SUMMARY

Report to:
DYMAPAK
PO Box 3332

New York, NY 10163

Samples of:	Secure Sack
Contract No.:	1371-346
Samples Received:	April 15, 2017
Submitted by:	Steve Annunziato

Objective

DYMAPAK submitted Secure Sack to determine if bag/closure would be compliant with the Consumer Product Safety Commission's current protocol and standards for poison prevention packaging Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Procedures

The protocol for evaluation of packaging for poison prevention (current C.F.R. Title 16, Part 1700.20) was strictly adhered to for this study.

Panelists

During this study 100 children (42 to 51 months of age) and 100 seniors (50 to 70 years-old, 70% female) were employed.

Results

Results of the study indicate that the Secure Sack meets the standards for poison prevention packaging per current C.F.R. Title 16 Part 1700.20.

II. INTRODUCTION

DYMAPAK wished to determine if Secure Sack fulfills Consumer Product Safety Commission's (CPSC) current standards and protocol for poison prevention packaging set forth in Code of Federal Regulations Title 16, Part 1700.20. Bitner Associates is recognized testing laboratory facility for testing child-resistant packaging according to CPSC protocol. They were requested to evaluate this package using the above-mentioned protocol.

Bitner Associates is an independent testing facility and has been evaluating child-resistant packaging for both industry and government for over twenty-five years. The company is recognized as a leader in the field by having employed hundreds of thousands of panelists and evaluated thousands of packaging concepts for child-resistance. Bitner Associates utilizes standard operating procedures (SOP's) along with quality assurance programs consistent with those acknowledged and supported by the Consumer Product Safety Commission and Environmental Protection Agency.

During this evaluation, the packaging was tested with panels consisting of 100 seniors (50 to 70 years old, 70% female) and 100 children (41 to 52 months of age, evenly distributed) obtained from nursery schools, day care centers and civic groups. Data derived from the study were assembled in a meaningful fashion and reviewed to determine whether the packaging met the cited standards for poison prevention packaging presented herein.

III. PROCEDURE

The following standard and protocol was adhered to in this study.

Protocol

Code of Federal Regulations Title 16, Part 1700:

1700.20 Testing procedure for testing special packaging.

(a) Test protocols - (1) General requirements - (i) Requirements for packaging. As specified in §1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this §1700.20.

(ii) Condition of packages to be tested. (A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies.

(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly re-secure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer packages is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package is not given to the test subject.

(B) Re-closable packages - adult tests. In both the adult tests, re-closable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to "take a set." If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) Child test - (i) Test subjects. (A) Selection criteria. Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in Table 1. No more than 20 percent of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40 percent of the children in each group shall be of age 45-48 months, and 30 percent of the children in each group shall be of age 49-51 months. The children's ages shall be calculated as follows:

(1) Arrange birth date and test date by numerical designations for month, day, and year.

(2) Subtract the month, day, and year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days.

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this value to the number of months that was obtained when the birth date was subtracted from the test date. This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

(4) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is -16 or less, subtract 1 month. If the number of days is between -15 and +15 inclusive, no change is made in the number of months.

(B) Gender distribution. The difference between the number of boys and the number of girls in each age range shall not exceed 10 percent of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. Each child's parent or guardian shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) Test failures. A test failure shall be any child who opens the special packaging or

Table 1. Number of Openings: Acceptance (Pass), Continue Testing, and Rejection (Fail) Criteria for the First 5 minutes and the Full 10 minutes of the Children's Protocol Test

Test Panel	Cumulative number of children	Package Openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1….	50	0 – 3	4 – 10	11+	0 – 5	6 – 14	15+
2….	100	4 – 10	11 – 18	19+	6 – 15	16 – 24	25+
3….	150	11 – 18	19 – 25	26+	16 – 25	26 – 34	35+
4….	200	19 – 30	…..	31+	26 – 40	…..	41+

gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of substance that may produce serious personal injury or serious illness shall be based on a 25-pound child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) Sequential test. The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in Table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30 percent of the children tested in each group. Table 1 gives the acceptance (pass), continue

testing, and rejection (fail) criteria to be used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in Table 1 are cumulative.

(iv) Test procedures. The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children; for example, their customary nursery school or regular kindergarten. No child shall test more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

Standardized Child Test Instructions

1. Re-closable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials, (e.g. the closure liner), to "take a set." Application torques must be recorded in the test report.

2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

3. Re-closable packages shall be opened and properly re-secured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and re-securing shall not be done in the presence of the children. (In the adult-re-securing test, the tester must not open and re-secure the package prior to the test.) If multiple openings/re-securings are to be used, each of four (4) testers shall open and properly re-secure one fourth of the packages once and then shall open and properly re-secure each package a second, third, fourth, through tenth (or other specified number) time, in the same sequence as the first opening and re-securing. The packages shall not be opened and re-secured again prior to testing. The name of each tester and the package numbers that he/she opens and re-secures shall be recorded and reported. It is not necessary for the tester to protocol test the packages that they opened and re-secured.

4. The child shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.

5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.

6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.

7. The tester shall talk to the children to make them feel at ease.

8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.

9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.

10. The tester shall use a stopwatch(s) or other timing device to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.

11. To begin the test, the tester shall hand the children identical packages and say, "PLEASE TRY TO OPEN THIS FOR ME."

12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversations with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., "please try to open the package").

14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).

15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the results.

16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.

17. A child shall not be allowed to try to open the other child's package.

18. If a child opens his/her package, the tester shall say, "THANK YOU," take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.

19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate "demo" package shall be used for the demonstration.

20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.

21. The tester shall say, "WATCH ME OPEN MY PACKAGE."

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, "NOW YOU TRY TO OPEN YOUR PACKAGES."

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, "YOU CAN USE YOUR TEETH IF YOU WANT TO." This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, "THANK YOU FOR HELPING." If children were told that they could use their teeth, the tester shall say, "I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH

AGAIN." In addition, the tester shall say, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

(3) Senior-adult panel - (i) Test subjects. Use a group of 100 senior adults. Not more than 24 percent of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50 - 54 years old age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability.

(ii) Screening procedures. Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or “special") closures. One closure shall be a plastic snap closure and the other a continuous threaded (CT) plastic closure. Each closure shall have a diameter of 28 mm ∀ 18%, and the CT closures shall have been re-secured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce ∀ ½ ounce for the CT-type closure and 8 drams ∀ 4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly re-secured the package in the 1-minute test period.

(iv) Test procedures. The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

Test Instructions for Senior Test

The following test instructions are used for all senior tests. If non-re-closable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability which would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Before

beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and re-secure the packages are the only exceptions.

6. To begin the first 5-minute test period, the tester says, "I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP." (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, "PLEASE OPEN THIS PACKAGE ACCORDING THE DIRECTIONS OF THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS OF THE CAP." (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and re-securing times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, "THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THIS PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

12. After the 1-minute test, or when the participant has opened and closed the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The times to open and re-secure or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and re-secure both of the non-child-resistant screening packages are not counted as part of the 100-senior panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

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 percent 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 re-secure 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 re-securing 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 re-secure the special packaging. The number of adults who successfully open the special packaging and then properly re-secure the special packaging (if re-securing 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.

(iii) Adult-use effectiveness of not less than 90 percent.

IV. TEST PARAMETERS

The Package

Test packages were Secure Sack. For purposes of this evaluation, all units tested were empty.

Opening Directions: Pictogram included.
TO OPEN:

1. Locate lip on front of bag with red dot
2. Hold hidden lip tightly between your thumb and forefinger
3. Hold the rear bag flap with your other had and insert your thumb into the opening as far as possible
4. Press knuckles of both thumbs together and hold tightly
5. Push thumb tips outward in opposite directions to open zipper

TO CLOSE:
Close the zipper firmly using both hands.

Panelists
In the child testing phase of this study, 100 children between the ages of 42 - 51 months distributed into three age groups (42-44, 45-48, and 49-51 months, distributed proportioned by age and gender) were employed. The 100 Bottles used for child testing were previously tested by seniors as required by CFR Title 16 Part 1700.20.

Seniors (100) employed in the study also satisfied the requirements of the protocol, with ages ranging from 50 to 70 years of age divided into three age groups (50-54, 55-59, and 60-70 years old with 70% female).

Test supervisor(s)
Test supervisor(s) were instructed to conduct the evaluation of the packaging in strict accordance with the current C.F.R. Title 16, Part 1700.20. To ensure these procedures were adhered to, our complete quality system was followed, including periodic observations throughout the package evaluation.

PHOTO: SECURE SACK

SPECIFICATIONS __

FILM: Polyethylene/Polyethylene Perephthalate

V. RESULTS AND DISCUSSION

Results of this study appear in the tables section of the report. These tables represent a compilation of all data obtained during the study. For clarity in presentation and discussion of this information, the following features will be used as the major points of discussion:

- Child-resistant effectiveness for children 42-51 months.
- Senior-use effectiveness – Senior Re-securing
- Adult Re-securing Test
- Meeting current Code of Federal Regulations Title 16, Part 1700.20

Child-resistant effectiveness

Results of the package evaluation by the 100 child panelists aged 42-51 months appear in Table 1 of the report. From Table 1 it will be noted that one of the children opened the package before demonstration and none of the children could remove the closure following demonstration for a total of 1 successful child panelists. This represents a child-resistant effectiveness of **99%.**

Senior Adult Use Effectiveness

Senior panel consisted of 70 females and 30 males. Results of the senior test appear in Table 2 of this report. A total of 25 of the 25 seniors in the 50 to 54-year-old age group were successful in opening the first package and opening and properly closing the second package, 25 of the 25 seniors in the 55 to 59-year-old age group were successful, and 48 of the 50 seniors were successful in the 60 to 70-year-old age group. The SAUE was calculated at **98%**.

Meeting current C.F.R. Title 16, Part 1700.20.

DYMAPAK's Secure Sack Consumer Product Safety Report meets standards for poison prevention packaging evaluation per current C.F.R. Title 16, Part 1700.02.

CONCLUSION

The data presented in report demonstrates that the Secure Sack meets requirements for poison prevention packaging according to current Code of Federal Regulations Title 16, Part 1700.20. Package performed well for senior adults, and one child could defeat it.

EVALUATION OF Secure Sack **AS A CHILD-RESISTANT PACKAGE**

Table 1. Evaluated by children 42 to 51 months of age for child resistant effectiveness

				Successful Panelists				
				Before Demonstration		After Demonstration		
Age in Months	**Males**	**Females**	**Total**	**Males**	**Females**	**Males**	**Females**	**Total**
42-44	14	16	30	1	0	0	0	1
45-48	20	20	40	0	0	0	0	0
49-51	14	16	30	0	0	0	0	0
TOTAL	**48**	**52**	**100**	**1**	**0**	**0**	**0**	**1**

CHILD-RESISTANT EFFECTIVENESS = 99%

CHILD DATA: 42 – 44 months							
	PKG #	**AGE**	**M/F**	**DoB**	**Tester**	**location**	**COMMENTS**
1.	36	44	M	8/14/2013	JBU	ACT	Pulled on opening
2.	52	43	M	9/20/2013	JBU	ACT	Played with bag
3.	12	43	M	9/14/2013	JBU	ACT	2:12
4.	02	44	M	8/21/2013	JBU	ACT	Pulled on opening
5.	10	43	M	9/24/2013	JBU	ACT	Twisted bag
6.	18	42	M	10/22/2013	JBU	ACT	
7.	56	42	M	10/21/2013	JBU	ACT	Twist bag
8.	84	43	M	9/23/2013	JF	LSG	"tricky"
9.	100	44	M	8/14/2013	JF	LSG	Twisted bag
10.	104	43	M	9/23/2013	JF	LSG	Pulled hard
11.	126	42	M	10/26/2013	JF	LSG	
12.	128	42	M	10/18/2013	JF	LSG	Tried to rip w/teeth
13.	138	42	M	10/15/2013	JF	LSG	Twisted bag
14.	172	42	M	10/29/2013	RB	EDC	Pulled real hard
15.	54	44	F	8/17/2013	JBU	ACT	Bit on bag

CHILD DATA: 42 – 44 months continued							
	PKG #	**AGE**	**M/F**	**DoB**	**Tester**	**Location**	**COMMENTS**
16.	44	44	F	8/20/2013	JB	ACT	Twisted bag
17.	60	43	F	9/19/2013	JF	LSG	Twisted bag/bit
18.	68	44	F	8/15/2013	JF	LSG	
19.	40	43	F	9/24/2013	JBU	BG	Bit the bag/pulled
20.	76	43	F	9/27/2013	JF	BG	
21.	82	42	F	10/21/2013	JF	BG	Twisted/pulled bag
22.	98	42	F	10/24/2013	JF	BG	Pick at opening
23.	112	42	F	10/14/2013	JF	BG	Twisted bag
24.	122	44	F	8/16/2013	JF	BG	Folded bag
25.	134	44	F	8/17/2013	JF	BG	Twisted bag
26.	174	42	F	10/28/2013	RB	EDC	Folded bag
27.	176	43	F	9/16/2013	RB	EDC	Pulled hard
28.	182	44	F	8/17/2013	RB	EDC	Twist bag
29.	142	43	F	9/16/2013	RB	EDC	Bit/pulled
30.	146	44	F	8/25/2013	RB	EDC	Rolled and crinkled

CHILD DATA: 45 – 48 months							
	PKG #	**AGE**	**M/F**	**DoB**	**Tester**	**Location**	**COMMENTS**
1.	26	48	M	4/21/2013	JBU	BG	Twisted bag
2.	08	49	M	3/18/2013	JBU	BG	Twisted/folded
3.	06	47	M	5/24/2013	JBU	BG	“Is this a napkin”
4.	32	46	M	6/23/2013	JBU	EDC	Pulled at top
5.	46	47	M	5/16/2013	JBU	EDC	Twisted bag
6.	74	46	M	6/25/2013	JF	EDC	Bit/pulled
7.	88	46	M	6/29/2013	JF	EDC	Twisted bag
8.	106	45	M	7/28/2013	JF	EDC	Twisted bag
9.	118	46	M	6/20/2013	JF	HAH	
10.	144	45	M	7/27/2013	RB	HAH	Pulled real hard
11.	178	46	M	6/21/2013	RB	HAH	Twisted bag
12.	180	47	M	5/19/2013	RB	HAH	
13.	148	45	M	7/25/2013	RB	HAH	Twisted/pulled
14.	150	47	M	5/20/2013	RB	HAH	Pulled real hard
15.	152	48	M	4/22/2013	RB	HAH	Bit/pulled
16.	184	45	M	7/26/2013	RB	HAH	Twisted bag
17.	194	46	M	6/10/2013	RB	HAH	
18.	154	47	M	5/17/2013	RB	HAH	Twisted bag
19.	160	48	M	4/27/2013	RB	HAHW	
20.	166	45	M	7/21/2013	RB	HAHW	Twisted bag
21.	38	46	F	6/20/2013	JBU	HAHW	Bit/pulled/w/teeth
22.	16	48	F	4/23/2013	JBU	HAHW	
23.	64	47	F	5/24/2013	JBU	HAHW	Twist bag

CHILD DATA: 45 – 48 months - continued							
	PKG #	**AGE**	**M/F**	**DoB**	**Tester**	**Location**	**COMMENTS**
24.	62	47	F	5/26/2013	JBU	HAHW	Twisted/pulled
25.	42	48	F	4/21/2013	JBU	HAHW	Twisted bag
26.	14	48	F	4/27/2013	JBU	HAHW	Twisted bag
27.	30	46	F	6/25/2013	JBU	HAHW	Pulled on seam
28.	20	45	F	7/27/2013	JBU	HAHW	Twisted
29.	78	45	F	7/19/2013	JF	KF	
30.	90	45	F	7/22/2013	JF	KF	Pulled real hard
31.	86	46	F	6/20/2013	JF	KF	Pulled real hard
32.	96	48	F	4/26/2013	JF	KF	Stood up/pulled
33.	102	46	F	6/11/2013	JF	CC	Twisted bag
34.	108	47	F	5/19/2013	JF	CC	Twisted bag
35.	114	45	F	7/16/2013	JF	CC	
36.	116	45	F	7/19/2013	JF	CC	Folded/crinkled
27.	130	47	F	5/18/2013	JF	CC	
38.	132	45	F	7/21/2013	JF	CC	Twisted bag
39.	140	47	F	5/20/2013	RB	ACF	
40.	186	45	F	7/18/2013	RB	ACF	Pulled hard

CHILD DATA: 49 – 51 months							
	PKG #	**AGE**	**M/F**	**DoB**	**Tester**	**Location**	**COMMENTS**
1.	50	49	M	3/19.2013	JBU	KF	Pulled real hard
2.	46	49	M	3/27/2013	JBU	KF	Twisted bag
3.	34	49	M	3/16/2013	JBU	KF	Twisted bag
4.	70	49	M	3/21/2013	JF	KF	Wanted to go
5.	72	49	M	3/17/2013	JF	CC	
6.	92	49	M	3/22/2013	JF	CC	Twisted bag
7,	110	49	M	3/20/2013	JF	CC	Twisted bag
8.	120	49	M	3/18/2013	JF	CC	
9.	124	49	M	3/17/2013	JF	KF	
10	168	49	M	3/23/2013	RB	KF	Twisted bag
11.	196	50	M	2/17/2013	RB	ACF	Twisted bag
12.	198	50	M	2/23/2013	RB	ACF	Folded
13.	162	50	M	2/26/2013	RB	ACF	Twisted bag
14.	164	50	M	2/23/2013	RB	ACF	Bit/pulled
15.	04	50	F	2/15/2013	JBU	ACF	Picked at top
16.	80	50	F	2/12/2013	JF	ACF	
17.	94	50	F	2/24/2013	JF	ACF	Twisted bag
18.	136	50	F	2/16/2013	JF	ACF	Pulled real hard
19.	188	50	F	2/20/2013	RB	GS	
20.	192	50	F	2/24/2013	RB	GS	Bit/Pulled
21.	190	51	F	1/16/2013	RB	GS	

CHILD DATA: 49 – 51 months continued							
	PKG #	**AGE**	**M/F**	**DoB**	**Tester**	**Location**	**COMMENTS**
22.	170	51	F	1/16/2013	RB	GS	Twisted bag
23.	200	51	F	1/18/2013	RB	GS	Pulled on top
24.	156	51	F	1/20/2013	RB	GS	Twisted bag
25.	158	51	F	1/20/2013	RB	GS	Twisted bag
26.	22	51	F	1/18/2013	DB	GS	Twisted bag
27.	58	51	F	1/16/2013	DB	GS	Twisted bag
28.	64	51	F	1/22/2013	DB	GS	"Mine is broke"
29.	48	51	F	1/17/2013	DB	KC	Twisted bag
30.	24	41	F	1/21/2013	DB	KC	Twisted bag

EVALUATION OF Secure Sack
FOR SENIOR EFFECTIVENESS

Table 2. Package opening test evaluated by adults 50 to 70 years of age

		Successful Panelists		
	Panelists Tested	**First Opening**	**Second Opening and Second Closing**	**TOTAL FAILURES**
50-54 years old:				
Females	17	17	17	0
Males	8	8	8	0
Subtotal	**25**	**25**	**25**	**0**
55-59 years old:				
Females	17	17	17	0
Males	8	8	8	0
Subtotal	**25**	**25**	**25**	**0**
60-70 years old:				
Females	35	35	33	2
Males	15	15	15	0
Subtotal	**50**	**50**	**48**	**0**
TOTAL	**100**	**100**	**98**	**2**

SENIOR-USE EFFECTIVENESS (SAUE) = 98% **ADULT RESECURING 100%**

SENIOR ADULT: 50 – 54 YEARS						
	PKG #s	**AGE**	**M/F**	**P/F**	**Times to Open**	**Tester**
1.	01/02	53	M	PASS	:11/:09	JBUC
2.	03/04	50	M	PASS	:10/:19	JBUC
3.	05/06	54	M	PASS	:10/:12	JBUR
4.	07/08	54	M	PASS	:12/:08	JBUR
5.	09/10	54	M	PASS	:11/:13	JBUR
6.	11/12	54	M	PASS	:16/:10	JBUR
7.	13/14	54	M	PASS	:21/;10	JBUR
8.	15/16	53	M	PASS	;20/:10	JBUR
9.	17/18	52	F	PASS	:21/:16	JBUC
10.	19/20	50	F	PASS	:09/:06	JBUC
11.	21/22	52	F	PASS	:17/:11	JBUC
12.	23/24	54	F	PASS	:16/:14	JBUC
13.	25/26	54	F	PASS	:12/:08	JBUR
14.	27/28	50	F	PASS	:15/:11	JBUR
15.	29/30	53	F	PASS	:11/:09	JBUR
16.	31/32	53	F	PASS	:10/:09	JBUR
17.	33/34	50	F	PASS	:26/:13	RB
18.	35/36	53	F	PASS	:20/:11	RB
19.	37/38	53	F	PASS	:10/:07	RB
20.	39/40	50	F	PASS	:11/:08	RB
21.	41/42	52	F	PASS	:18/:06	RB
22.	43/44	53	F	PASS	:17/:14	RB
23.	45/46	51	F	PASS	:16/:09	JR
24.	47/48	50	F	PASS	:17/:08	JB
25.	49/50	54	F	PASS	:11/:15	JB

SENIOR ADULT: 55 – 59 YEARS						
	PKG #s	**AGE**	**M/F**	**P/F**	**Times to Open**	**Tester**
1.	51/52	56	M	PASS	:14/:08	JBUC
2.	53/54	55	M	PASS	:14/:11	JBUC
3.	55/56	58	M	PASS	:10/:14	JBUC
4.	57/58	57	M	PASS	:16/:10	JBUR

SENIOR ADULT: 55 -59 YEARS - continued						
	PKG #s	**AGE**	**M/F**	**P/F**	**Times to Open**	**Tester**
5.	59/60	58	M	PASS	:13/:09	JBUR
6.	61/62	57	M	PASS	:16/:09	JBUR
7.	63/64	57	M	PASS	:10/:07	JBUR
8.	65/66	57	M	PASS	:07/:07	JBUR
9.	67/68	59	F	PASS	;11/:06	JBUR
10.	69/70	57	F	PASS	:15/:09	JBUR
11.	71/72	55	F	PASS	:11/:11	JBUR
12.	73/74	56	F	PASS	:45/:35	RB
13.	75/76	58	F	PASS	:10/:06	JBUR
14.	77/78	57	F	PASS	:25/:20	RB
15.	70/80	57	F	PASS	:10/:12	RB
16.	81/82	58	F	PASS	:21/:15	RB
17.	83/84	59	F	PASS	:18/:13	RB
18.	85/86	58	F	PASS	:40/:23	RB
19.	87/88	59	F	PASS	:18/:24	RB
20.	89/90	59	F	PASS	:16/:14	RB
21.	91/92	55	F	PASS	:13/:09	JBUR
22.	93/94	57	F	PASS	:13/:08	JBUR
23.	95/96	56	F	PASS	:13/:07	JBUR
24.	97/98	59	F	PASS	:26/:20	JBUC
25.	99/100	55	F	PASS	:19.:11	DB

SENIOR ADULT: 60 - 70 YEARS						
	PKG #s	**AGE**	**M/F**	**P/F**	**Times to Open**	**Tester**
1.	101/102	68	M	PASS	:25/:15	JBUC
2.	103/104	60	M	PASS	:24/:16	JBUC
3.	105/106	64	M	PASS	:12/:08	JBUC
4.	107/108	68	M	PASS	:16/:18	JBUC
5.	109/110	61	M	PASS	:18/:12	JBUC
6.	111/112	64	M	PASS	:17/:12	JBUC
7.	113/114	67	M	PASS	:12/:10	JBUC
8.	115/116	61	M	PASS	:10/:09	JBUC
9.	117/118	67	M	PASS	:14/:10	JBUC
10.	119/120	61	M	PASS	:17/:12	JBUC
11.	121/122	60	M	PASS	:11/:08	JBUC
12.	123/124	60	M	PASS	:17/:11	JBUC
13.	125/126	67	M	PASS	:26/:21	JBUC

SENIOR ADULT: 60 - 70 YEARS continued						
	PKG#s	**AGE**	**M/F**	**P/F**	**Times to Open**	**Tester**
14.	127/128	64	M	PASS	:17/:11	JBUC
15.	129/130	66	M	PASS	:14/:09	JBUC
16.	131/132	70	F	PASS	:31/:26	JBUC
17.	133/134	61	F	PASS	:11/:10	JBUC
18.	135/136	66	F	PASS	:14/:12	JBUC
19.	137/138	60	F	PASS	:08/:09	JBUR
20.	139/140	63	F	PASS	:13/:08	JBUR
21.	141/142	64	F	PASS	:11/:13	JBUR
22.	143/144	62	F	PASS	:12/:06	JBUR
23.	145/146	69	F	PASS	:07/:06	JBUR
24.	147/148	65	F	PASS	:19/:10	JBUR
25.	149/150	60	F	PASS	:06/:06	JBUR
26.	151/152	63	F	PASS	:10/:06	JBUR
27.	153/154	69	F	PASS	:07/:06	JBUR
28.	155/156	62	F	PASS	:40/:44	RB
29.	157/158	62	F	FAIL	2:00/1:06	RB
30.	159/160	63	F	PASS	1:18/1:11	RB
31.	161/162	70	F	PASS	:50/:42	RB
32.	163/164	70	F	PASS	:48/:48	RB
33.	165/166	67	F	PASS	:15/:20	RB
34.	167/168	69	F	PASS	:48/:37	RB
35.	169/170	67	F	PASS	:08/:13	RB
36.	171/172	69	F	PASS	:51/:33	RB
37.	173/174	62	F	PASS	:21/:11	RB
38.	175/176	66	F	PASS	:16/:14	RB
39.	177/178	64	F	PASS	:11/:11	RB
40.	179/180	69	F	PASS	:31/:23	RB
41.	181/182	62	F	PASS	:17/:10	RB
42.	183/184	62	F	PASS	:08/:11	RB
43.	185/186	69	F	PASS	:37/:37	RB
44.	187/188	63	F	PASS	:12/:12	RB
45.	189/190	64	F	PASS	:58/:47	RB
46.	191/192	65	F	PASS	:23/:28	RB
47.	193/194	61	F	PASS	:17/:15	RB
48.	195/196	62	F	PASS	:18/:19	RB
49.	197/198	65	F	PASS	:30/:33	RB
50.	199/200	70	F	PASS	1:32/:46	RB

GENERAL OBSERVATIONS:

SENIORS
Some of the adults had a little bit of a challenging time mainly because they did not take the time to read the directions. They did wonder what would be going inside the package Testing was conducted from April 20 thru April 24, 2017.

CHILDREN
The children had a lot of trouble with this product. They bit on the bag while pulling as hard as they could. They tried to rip the bag with no success, some of the children folded the bag and other "crinkled" the bag. The children were tested from April 21 thru April 26, 2017.

Test Supervisors

- Julie Ford
- Jen Burton
- Jeremy Brooks
- Debra Bitner
- John Buckner
- Raechel Buckner

TREAD GLOBAL
International Product Sourcing and Development

POISON PREVENTION PACKAGING

Test Report for

SECURE SACK

March 23, 2018

Conducted For

DYMAPAK

DYMAPAK

TREAD GLOBAL
International Product Sourcing and Development

999 18th Street, Suite 3000, Denver, CO 80202
www.TreadGlobal.com Phone (303) 993-8943

March 23, 2018

Steven Annunziato, COO
Dymapak
725 River Road, Suite 213
Edgewater, NJ 07020

Dear Mr. Annunziato:

Attached is our report of the Poison Prevention Packaging testing that has been completed for your product, the Secure Sack.

Your product has been evaluated using the Consumer Product Safety Commission's protocol and standards. The test results show clearly that Secure Sack fulfills the requirements for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700.

In the testing of the Secure Sack none of the senior adults failed to open the package, a 100% effectiveness rate. One child was able to open the package, a child-resistant effectiveness of 98%.

I look forward to reviewing your report results with you at your convenience.

Sincerely,

Jeremiah Buck
Director of Product Development
Tread Global, Inc.

Participating Member ASTM, #1747717
Member of Child-Resistant Packaging Sub-Committee

TREAD GLOBAL, INC.
POISON PREVENTION PACKAGING TEST REPORT FOR
THE SECURE SACK
March 23, 2018

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TREAD GLOBAL
International Product Sourcing and Development

999 18th Street, Suite 3000, Denver, CO 80202
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REPORT SYNOPSIS

March 23, 2018

Report issued to: Steven Annunziato, COO
Dymapak
725 River Road, Suite 213
Edgewater, NJ 07020

Product tested: Secure Sack

Manufacturer: Quark Distribution, Inc.

Testing dates: Testing began March 1, 2018
Testing ended March 21, 2018

Objective

Dymapak submitted the Secure Sack for analysis to determine if the package is in compliance with the Consumer Product Safety Commission's (CPSC) protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700, including Part 1700.15 (1995) and Part 1700.20 (1995). (see Addendum)

Procedures

The protocols for the evaluation of packaging for poison prevention (CFR Title 16, Part 1700) were strictly adhered to for this study, unless otherwise documented.

Participants

In the course of this study, 50 children (42 to 51 months of age) and 100 senior adults (50 to 70 years old, 70% female) were employed.

Results

Results of this study indicate that the Secure Sack meets and exceeds the standards for Poison Prevention Packaging as required by CFR Title 16, Part 1700.

Tread Global, Inc. is recognized in the field of consumer product testing and development, and has been employed by Dymapak to ascertain if their product, the Secure Sack, fulfills the Consumer Product Safety Commission's (CPSC) standards for Poison Prevention Packaging as set forth in CFR Title 16, Part 1700.

Tread Global, Inc. is an independent product development company who also provides various testing services for a wide range of consumer products. Affordable Testing Solutions Limited, administrators of this test, has years of extensive experience performing tests for consumer product safety, and specializes in child related safety testing as required in CFR Title 16, Part 1700. Testing was performed according to CPSC protocol.

Tread Global, Inc. utilizes standard operating procedures along with quality assurance programs consistent with the protocols acknowledged and supported by the Consumer Product Safety Commission.

“Child-resistant packaging” means packaging that is designed and constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

In the course of this evaluation, the packaging was tested with participants consisting of 100 senior adults (50 to 70 year-olds, 70% female) and 50 children (42 to 51 months of age, evenly distributed by gender). The data derived from the study was compiled and reviewed to determine whether the packaging met the cited standards for Poison Prevention Packaging presented herein. (See Tables 1 and 2, and Testing Results Summary)

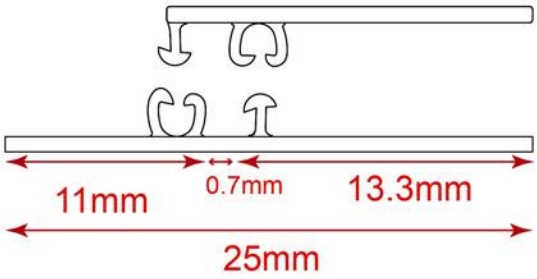
The Package

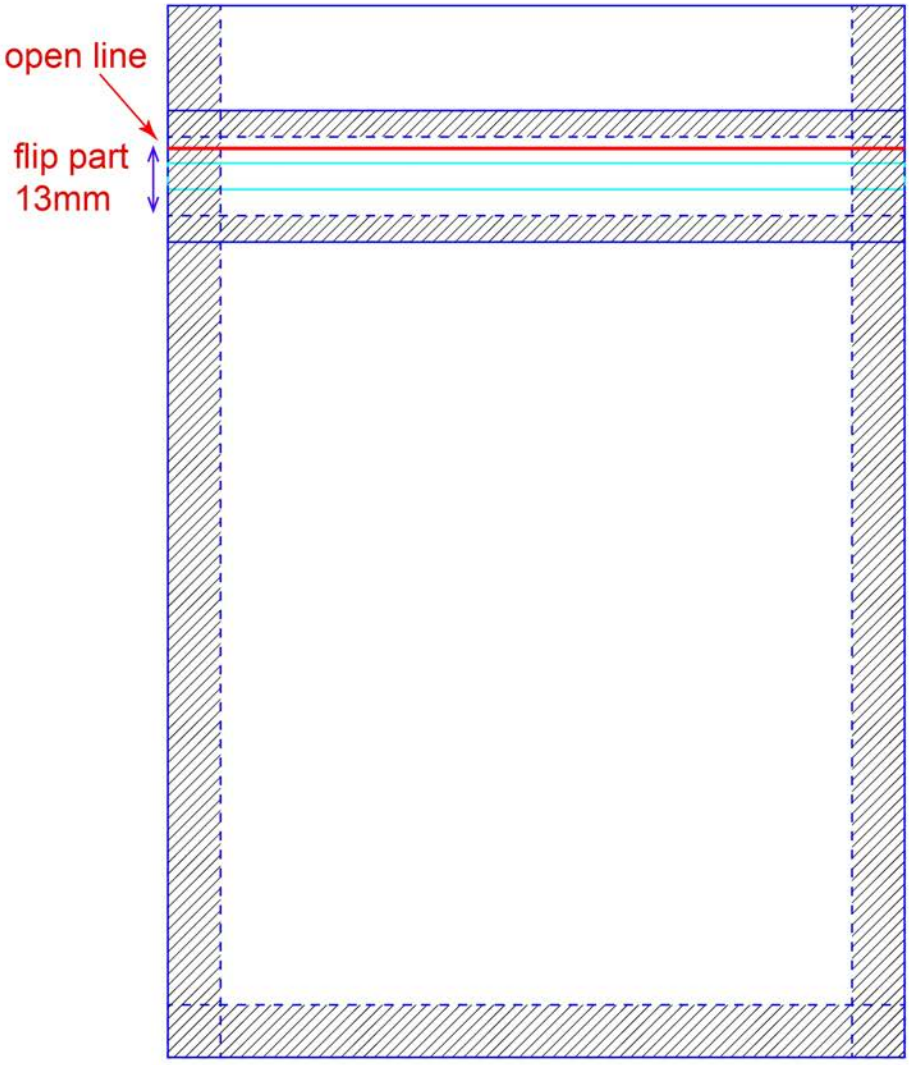
The package submitted for testing was the Secure Sack, a 12" x 9" package with a 4" bottom gusset. The package has a black exterior and silver interior, is heat sealed on three sides with a double press and seal zipper at the top. The zipper is opened by pulling a flap on one side of the package and the top opening of the opposite side. (See photos below.) Dymapak reports that the package is constructed of a film of polyethylene (PE), a thermoplastic and polyethylene terephthalate (PET), a thermoplastic polymer resin; the zipper is constructed of polypropylene (PP), a thermoplastic polymer. Graphic opening instructions are below the zipper (See photo below.) This configuration is referred to in this report as the “Secure Sack”, “the package” or “the container”.

The Secure Sack is intended to contain various cannabis products.

For purposes of this test, each participant was given a new package that had never been opened. All of the units were empty. The Test Administrators asked all adult participants to open and reclose the package properly; the children were asked to open the package.

Continued





Continued

Participants

In the children's testing phase, 50 children were employed between the ages of 42 and 51 months and were divided into three age groups (42-44, 45-48, and 49-51 months, evenly distributed by gender).

In the senior adult's testing phase, 100 senior adults were employed with ages ranging from 50 to 70 years of age, divided into three age groups (50-54, 55-59, and 60-70 years of age, 70% female).

Test Administrators

Test Administrators were instructed to conduct the evaluation of the packaging in strict accordance with the standards and protocols required by the CFR Title 16, Part 1700, unless otherwise documented. The Test Administrators asked all adult participants to open and reclose the package properly; the children were asked to open the package.

Materials

The Secure Sack is manufactured by Quark Distribution, Inc. for Dymapak.

The package is constructed of a film of polyethylene (PE), a thermoplastic used for its low reactivity at room temperature, flexibility, and versatile chemical and water resistance, and polyethylene terephthalate (PET), a thermoplastic polymer resin used for its good gas, moisture and solvent barrier, strength and impact-resistance, as well as being lightweight. The zipper is constructed of polypropylene (PP), a thermoplastic polymer used for its high resistance to chemical solvents, bases, acids, and moisture, and good fatigue resistance.

Individual results of this study appear in the Data Evaluation section of this report. The tables presented represent a compilation of all data obtained during the study. For clarity in presentation and discussion of this information, the following features will be used as the major points of discussion:

* Child-resistant effectiveness
* Senior adult use effectiveness (SAUE)
* Code Requirements

Child-Resistant Effectiveness

Results of the children's testing appear in Table 1 of this report. This Table demonstrates that one child was able to open the Secure Sack during the second five minute testing period, a 2% failure rate and a child-resistant effectiveness of 98% for the entire testing, exceeding the CFR Title 16, Part 1700 minimum requirements.

Senior Adult Use Effectiveness

Results of the senior adult's testing appear in Table 2 of this report. This Table shows that all of the senior adult participants were successful in opening the Secure Sack. The SAUE was calculated at 100%, exceeding the CFR Title 16, Part 1700 minimum requirements.

Code Requirements

The results of the testing of the Secure Sack show conclusively that the package meets the Consumer Product Safety Commission's (CPSC) protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700.

Test Results and Evaluation

Table 1

**Summary of Package Opening Test Results for the Secure Sack
Evaluated by Children 42 to 51 Months of Age
For Child-Resistant Effectiveness**

				Successful Package Openings				
				First Test Period		Second Test Period		
Age in Months	Males	Females	Total	Males	Females	Males	Females	Total
42-44	7	8	15	0	0	0	0	0
45-48	10	10	20	0	0	1	0	1
49-51	8	7	15	0	0	0	0	0
Total	**25**	**25**	**50**	**0**	**0**	**1**	**0**	**1**

Per CPSC protocol, children are allowed up to five minutes to open the package in each of two testing periods.

A test is considered failed when any child opens the special packaging or gains access to its contents within the time allotted.

Times for failed tests are listed as “minutes : seconds”.

Test Results and Evaluation, continued

Children's Data, 42-51 Months, Secure Sack

Test #	Age in Months	Gender	Pass/ Failed Time	Test Site	Tester
1	44	M	Pass	3	1
2	43	M	Pass	9	3
3	43	M	Pass	9	3
4	42	M	Pass	4	3
5	44	M	Pass	6	2
6	42	M	Pass	1	5
7	43	M	Pass	7	5
8	42	F	Pass	3	1
9	44	F	Pass	3	1
10	43	F	Pass	11	3
11	43	F	Pass	4	3
12	42	F	Pass	12	4
13	42	F	Pass	2	4
14	44	F	Pass	6	2
15	43	F	Pass	4	4
16	47	M	Pass	3	1
17	46	M	Pass	3	1
18	45	M	Pass	9	3
19	47	M	Pass	4	1
20	48	M	Pass	12	4
21	47	M	Pass	6	2
22	46	M	Pass	2	2
23	46	M	Pass	13	5
24	48	M	Pass	7	5
25	47	M	Failed at 1:16, second test	4	4

Test Results and Evaluation, continued

Children's Data, 42-51 Months, Secure Sack, continued

Test #	Age in Months	Gender	Pass/ Failed Time	Test Site	Tester
26	46	F	Pass	3	1
27	47	F	Pass	9	3
28	45	F	Pass	8	3
29	45	F	Pass	4	3
30	47	F	Pass	4	1
31	45	F	Pass	12	4
32	48	F	Pass	2	4
33	46	F	Pass	1	2
34	47	F	Pass	4	4
35	46	F	Pass	1	5
36	49	M	Pass	3	1
37	49	M	Pass	9	3
38	50	M	Pass	11	3
39	51	M	Pass	4	1
40	50	M	Pass	1	4
41	49	M	Pass	7	5
42	51	M	Pass	7	5
43	49	M	Pass	4	4
44	50	F	Pass	3	1
45	51	F	Pass	8	3
46	49	F	Pass	4	3
47	49	F	Pass	6	2
48	51	F	Pass	2	4
49	50	F	Pass	1	4
50	51	F	Pass	1	5

Test Results and Evaluation, continued

Children's Data, 42-51 Months, Secure Sack, continued

Test Results and Evaluation, continued

Table 2

Summary of Package Opening Test Results for Secure Sack
Evaluated by Senior Adults Age 50-70 Years
For Senior Adult Use Effectiveness

		Successful Package Openings		
Age and Gender	**Participants Tested**	**First Opening**	**Second Opening**	**Total Failures**
50-54 years old:				
Females	18	18	4	0
Males	7	7	1	0
Subtotal	**25**	**25**	**5**	**0**
55-59 years old:				
Females	17	17	4	0
Males	8	8	2	0
Subtotal	**25**	**25**	**6**	**0**
60-70 years old:				
Females	35	35	11	0
Males	15	15	3	0
Subtotal	**50**	**50**	**14**	**0**
Total	**100**	**100**	**25**	**0**

Per CPSC protocol, in order to pass the first testing period, participants are allowed up to five minutes to open and reclose the package. In order to pass the second testing period, participants are allowed one minute to open and reclose the package. Participants who opened and reclosed the package in under one minute in the first testing period were not tested a second time.

A senior adult test is considered failed when any adult is unable to open and reclose the package within five minutes during the first test period, or is unable to open and reclose the package within one minute during the second test period.

In the following tables, adults were asked to rate the degree of difficulty of opening the package using the terms "Easy, Medium, or Hard".

Times are recorded as "minutes : seconds".

Test Results and Evaluation, continued

Senior Adult Data, 50-54 Years, Secure Sack

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
1	52	M	0:37	0:06	n/a	n/a	Pass	Easy	8	3
2	50	M	0:28	0:05	n/a	n/a	Pass	Easy	8	1
3	53	M	0:45	0:09	n/a	n/a	Pass	Easy	10	4
4	50	M	0:23	0:05	n/a	n/a	Pass	Easy	11	3
5	51	M	0:57	0:12	0:04	0:08	Pass	Easy	14	3
6	53	M	0:35	0:07	n/a	n/a	Pass	Easy	2	1
7	54	M	0:19	0:04	n/a	n/a	Pass	Easy	16	5
8	50	F	0:38	0:10	n/a	n/a	Pass	Easy	9	4
9	52	F	0:54	0:08	0:05	0:11	Pass	Easy	8	3
10	53	F	0:50	0:06	n/a	n/a	Pass	Medium	11	3
11	53	F	0:29	0:11	n/a	n/a	Pass	Easy	5	5
12	54	F	0:46	0:08	n/a	n/a	Pass	Easy	5	5
13	51	F	1:08	0:07	0:08	0:06	Pass	Easy	4	1
14	53	F	0:18	0:05	n/a	n/a	Pass	Easy	12	4
15	51	F	0:39	0:04	n/a	n/a	Pass	Easy	12	4
16	52	F	0:49	0:10	n/a	n/a	Pass	Medium	6	2
17	54	F	0:38	0:07	n/a	n/a	Pass	Easy	6	2
18	54	F	0:51	0:06	n/a	n/a	Pass	Easy	13	5
19	50	F	0:45	0:09	n/a	n/a	Pass	Easy	13	5
20	51	F	1:06	0:15	0:12	0:13	Pass	Medium	13	5
21	53	F	0:40	0:08	n/a	n/a	Pass	Easy	2	1
22	51	F	0:38	0:04	n/a	n/a	Pass	Easy	1	1
23	50	F	1:13	0:08	0:03	0:09	Pass	Easy	15	1
24	52	F	0:35	0:03	n/a	n/a	Pass	Easy	16	5
25	54	F	0:48	0:09	n/a	n/a	Pass	Easy	16	5

Test Results and Evaluation, continued

Senior Adult Data, 55-59 Years, Secure Sack

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
26	58	M	0:44	0:05	n/a	n/a	Pass	Easy	10	4
27	55	M	0:32	0:07	n/a	n/a	Pass	Easy	8	1
28	55	M	0:26	0:10	n/a	n/a	Pass	Easy	8	1
29	56	M	1:09	0:06	0:08	0:05	Pass	Easy	11	3
30	59	M	0:38	0:04	n/a	n/a	Pass	Easy	11	3
31	57	M	0:48	0:08	n/a	n/a	Pass	Easy	13	5
32	56	M	0:20	0:07	n/a	n/a	Pass	Easy	15	1
33	55	M	0:57	0:12	0:05	0:08	Pass	Easy	16	5
34	57	F	0:40	0:08	n/a	n/a	Pass	Easy	9	3
35	56	F	0:43	0:06	n/a	n/a	Pass	Easy	9	4
36	58	F	1:16	0:09	0:13	0:17	Pass	Medium	11	3
37	59	F	0:24	0:05	n/a	n/a	Pass	Easy	5	5
38	56	F	0:32	0:10	n/a	n/a	Pass	Easy	5	5
39	55	F	0:28	0:04	n/a	n/a	Pass	Easy	4	1
40	57	F	0:41	0:08	n/a	n/a	Pass	Easy	4	3
41	55	F	0:46	0:05	n/a	n/a	Pass	Medium	12	4
42	56	F	1:03	0:13	0:06	0:10	Pass	Easy	6	2
43	58	F	0:28	0:05	n/a	n/a	Pass	Easy	13	5
44	55	F	0:56	0:09	0:04	0:08	Pass	Easy	13	5
45	57	F	0:17	0:10	n/a	n/a	Pass	Easy	2	1
46	56	F	0:48	0:07	n/a	n/a	Pass	Medium	15	1
47	58	F	0:33	0:06	n/a	n/a	Pass	Easy	15	1
48	57	F	1:00	0:05	0:03	0:10	Pass	Medium	15	1
49	57	F	0:47	0:08	n/a	n/a	Pass	Easy	16	5
50	56	F	0:38	0:06	n/a	n/a	Pass	Easy	1	5

Test Results and Evaluation, continued

Senior Adult Data, 60-70 Years, Secure Sack

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
51	64	M	0:50	0:08	n/a	n/a	Pass	Easy	3	1
52	63	M	0:43	0:07	n/a	n/a	Pass	Easy	8	3
53	68	M	0:39	0:06	n/a	n/a	Pass	Easy	8	1
54	70	M	1:11	0:10	0:06	0:07	Pass	Easy	8	1
55	60	M	0:18	0:08	n/a	n/a	Pass	Medium	10	4
56	66	M	0:45	0:05	n/a	n/a	Pass	Easy	2	4
57	69	M	0:58	0:09	0:07	0:06	Pass	Easy	11	3
58	65	M	0:40	0:04	n/a	n/a	Pass	Easy	11	3
59	62	M	0:28	0:07	n/a	n/a	Pass	Easy	14	3
60	68	M	0:37	0:05	n/a	n/a	Pass	Easy	6	2
61	70	M	1:16	0:14	0:09	0:10	Pass	Medium	13	5
62	65	M	0:44	0:08	n/a	n/a	Pass	Easy	2	1
63	63	M	0:51	0:04	n/a	n/a	Pass	Easy	15	1
64	64	M	0:42	0:12	n/a	n/a	Pass	Easy	16	5
65	66	M	0:36	0:07	n/a	n/a	Pass	Easy	16	5
66	61	F	0:53	0:08	0:06	0:06	Pass	Easy	8	3
67	67	F	0:40	0:06	n/a	n/a	Pass	Easy	8	3
68	70	F	1:24	0:15	0:16	0:15	Pass	Medium	8	1
69	63	F	0:49	0:09	n/a	n/a	Pass	Easy	10	4
70	66	F	0:26	0:07	n/a	n/a	Pass	Easy	11	3
71	70	F	0:38	0:13	n/a	n/a	Pass	Easy	11	3
72	65	F	1:06	0:08	0:07	0:09	Pass	Medium	11	3
73	62	F	0:47	0:09	n/a	n/a	Pass	Easy	5	5
74	66	F	0:35	0:07	n/a	n/a	Pass	Easy	5	5
75	68	F	1:04	0:10	0:05	0:08	Pass	Easy	5	5

Test Results and Evaluation, continued

Senior Adult Data, 60-70 Years, Secure Sack, continued

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
76	64	F	0:45	0:12	n/a	n/a	Pass	Medium	5	5
77	64	F	0:36	0:08	n/a	n/a	Pass	Easy	4	1
78	60	F	0:29	0:11	n/a	n/a	Pass	Easy	4	1
79	69	F	0:57	0:06	0:04	0:10	Pass	Easy	4	3
80	65	F	0:40	0:10	n/a	n/a	Pass	Easy	4	3
81	62	F	0:31	0:04	n/a	n/a	Pass	Easy	14	3
82	66	F	0:48	0:06	n/a	n/a	Pass	Easy	12	4
83	70	F	1:06	0:08	0:11	0:05	Pass	Medium	12	4
84	67	F	0:50	0:05	n/a	n/a	Pass	Medium	12	4
85	62	F	0:20	0:07	n/a	n/a	Pass	Easy	12	4
86	68	F	0:26	0:11	n/a	n/a	Pass	Easy	12	4
87	62	F	0:54	0:06	n/a	n/a	Pass	Medium	6	2
88	70	F	1:13	0:07	0:16	0:13	Pass	Medium	6	2
89	61	F	0:46	0:04	n/a	n/a	Pass	Easy	6	2
90	64	F	0:34	0:05	n/a	n/a	Pass	Easy	13	5
91	69	F	0:57	0:08	0:07	0:07	Pass	Easy	13	5
92	60	F	0:29	0:13	n/a	n/a	Pass	Easy	2	1
93	66	F	0:45	0:05	n/a	n/a	Pass	Medium	15	1
94	61	F	0:26	0:08	n/a	n/a	Pass	Easy	15	1
95	68	F	0:43	0:11	n/a	n/a	Pass	Easy	15	1
96	62	F	0:56	0:05	0:05	0:06	Pass	Medium	15	1
97	70	F	1:24	0:12	0:09	0:08	Pass	Easy	16	5
98	65	F	0:36	0:05	n/a	n/a	Pass	Easy	16	5
99	61	F	1:15	0:09	0:10	0:11	Pass	Medium	16	5
100	64	F	0:44	0:07	n/a	n/a	Pass	Easy	16	5

Test Results and Evaluation, continued

Senior Adult Data, 50-70 Years, Secure Sack, continued

TREAD GLOBAL, INC.
TESTING RESULTS SUMMARY
March 23, 2018

Adult Testing Results

Following is a summary of the adult testing results per CFR Title 16, Part 1700:

Total packages opened	125
Total packages resecured	125
Total packages opened by males	36
Total packages resecured by males	36
Total packages opened by females	89
Total packages resecured by females	89

Mean opening times for total openings	37.1s
Standard deviation for total opening times	20.2s
Mean opening times for total openings by males	35.9s
Standard deviation for total opening times by males	18.8s
Mean opening times for total openings by females	37.6s
Standard deviation for total opening times by females	20.7s

Mean resecuring times for total resecurings	7.9s
Standard deviation for total resecuring times	2.8s
Mean resecuring times for total resecurings by males	7.4s
Standard deviation for total resecuring times by males	2.5s
Mean resecuring times for total resecurings by females	8.2s
Standard deviation for total resecuring times by females	2.9s

Adult Testing Results, continued

The Percentage of Packages Tested Per Site (not to exceed 24%)

Site 1	2%
Site 2	6
Site 3	1
Site 4	7
Site 5	8
Site 6	7
Site 8	11
Site 9	3
Site 10	4
Site 11	10
Site 12	8
Site 13	9
Site 14	3
Site 15	10
Site 16	11
	100%

The Percentage of Packages Tested Per Tester (not to exceed 35%)

Tester 1, CZ	27%
Tester 2, LL	7
Tester 3, EY	22
Tester 4, DC	15
Tester 5, CX	29
	100%

TREAD GLOBAL, INC.
TESTING RESULTS SUMMARY
March 23, 2018

Children's Testing Results

Following is a summary of the children's testing results per CFR Title 16, Part 1700:

	First Opening	Second Opening
Total packages opened	0	1
Total packages opened by males, 42-44 months	0	0
Total packages opened by males, 45-48 months	0	1
Total packages opened by males, 49-51 months	0	0
Total packages opened by females, 42-44 months	0	0
Total packages opened by females, 45-48 months	0	0
Total packages opened by females, 49-51 months	0	0

Mean opening times for total openings	76.0s
Standard deviation for total opening times	n/a

Children's Testing Results, continued

The Percentage of Packages Tested Per Site (not to exceed 24%)

Site 1	12%
Site 2	8
Site 3	16
Site 4	22
Site 6	8
Site 7	8
Site 8	4
Site 9	10
Site 11	4
Site 12	6
Site 13	2
	100%

The Percentage of Packages Tested Per Tester (not to exceed 35%)

Tester 1, CZ	22%
Tester 2, LL	12
Tester 3, EY	26
Tester 4, DC	24
Tester 5, CX	16
	100%

Children

The children in this study attempted to open the package by using their fingers, fingernails and teeth to pull on the top flaps and the bottom gusset. Only one child was successful in opening the package. It appears that the skills needed to open the package exceed the cognitive abilities, strength, and motor development of most children in this age group.

Senior Adults

All senior adult participants were successful in opening and reclosing the package within the time allotted. In rating the difficulty of opening the package, 81% of the participants reported that it was easy to open.

Conclusion

The results of this study indicate the Secure Sack meets the requirements for child-resistant effectiveness and senior adult use effectiveness as required by the CPSC, CFR Title 16, Part 1700 for Poison Preventive Packaging.

Scope of Work

The scope of work for this analysis was subject to CFR Title 16, Part 1700. Durability testing was performed by opening and closing a package 50 times. Administrators found that this resulted in no noticeable adverse affect to the zipper or the bag, thereby continuing to provide a secure closure.

This study did not further analyze material differences, long or short term deterioration to any part or aspect of the container, actual or hypothetical.

Intended Use of Report

The intended use of this report is for the client, Dymapak, to evaluate their product, the Secure Sack, subject to the Code of Federal Regulations Title 16, Part 1700, for child-resistant effectiveness and senior adult use effectiveness.

Intended User

The intended user of this report is Dymapak for the purpose of certification of their product, the Secure Sack, for compliance as Poison Prevention Packaging as prescribed by CFR Title 16, Part 1700. Consent must be obtained from Tread Global, Inc. before this report may be disclosed or distributed to any other party including, but not limited to, the public through advertising, public relations, news, sales, or other media.

The Consumer Product Safety Commission places the responsibility for performance of specialized packaging, such as child-resistant packaging, on the manufacturer and packager. It is therefore the obligation of Dymapak to oversee the production and implementation of this product to insure its proper performance.

Continued

Tread Global, Inc., its Test Administrators, advisors, industry professionals, supervisors or any others representatives employed or consulted will not be responsible for matters of a legal nature that affect the product, except for information that he or she became aware of during the research involved in performing this test summary. Tread Global, Inc. and its representatives will not give testimony or appear in court because he or she conducted a test on the product in question, unless specific arrangements to do so have been made beforehand, or as otherwise required by law.

The industry professionals do not, nor will not approve, certify or endorse any specific child-resistant package. It is assumed that adults have access to and use of various tools to open packages. It is also assumed that all such tools are kept out of the reach of children.

Tread Global, Inc. has not knowingly withheld any significant information from this report and all statements and information in this report are true and correct.

Dymapak is advised to discuss matters of protocol concerns, testing, various requisite regulations, and certification with legal counsel.

Design, materials, manufacturing variances (such as color, size, printing, labeling, etc.), and other external influences could have an adverse effect on the performance of this child-resistant package if different than the packages provided to Tread Global, Inc. for testing. Child-resistant packages may not perform as tested when exposed to different conditions of application, storage, handling, or other variables. All package samples for testing and package material specifications have been provided by Dymapak.

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GENERAL CERTIFICATE OF CONFORMITY

The Secure Sack

Dymapak certifies that the test unit, the Secure Sack, was evaluated and tested by a third party laboratory using the Consumer Product Safety Commission's protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700, including Part 1700.15 (1995) and Part 1700.20 (1995).

Tread Global, Inc. found the results of the study indicate that the test unit, the Secure Sack, fulfills the requirements for child-resistant effectiveness and senior adult use effectiveness as required by the Code of Federal Regulations (CFR) Title 16, Part 1700, including Part 1700.15 (1995) and Part 1700.20 (1995), for Poison Prevention Packaging.

Effective Date: March 23, 2018

DYMAPAK

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China, February 2018

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Participating Member ASTM, #1757717
Member of Child-Resistant Packaging Sub-Committee

COMPLIANCE STATEMENT

It is hereby certified that all materials used in the manufacture of parts in the quantity called for on the subject purchase order conforms to the materials and/or manufacturing specifications indicated in drawings or specifications as called for on said purchase order.

The Secure Sack, manufactured by Quark Distribution, Inc. for Dymapak, is in compliance with the Poison Prevention Act of the United States of America. (See Test Report "Secure Sack".)

Standards and Protocol

As published from the United States Government Printing Office:

Code of Federal Regulations

Title 16 - Commercial Practices

Volume: 2
Date: 2012-01-01
Original Date: 2012-01-01
Title: PART 1700 - POISON PREVENTION PACKAGING
Context: Title 16 - Commercial Practices. CHAPTER II - CONSUMER PRODUCT SAFETY COMMISSION. SUBCHAPTER E - POISON PREVENTION PACKAGING ACT OF 1970 REGULATIONS.

Pt. 1700

PART 1700—POISON PREVENTION PACKAGING

Sec.

Authority: 15 U.S.C. 1471-76. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).
Source: 38 FR 21247, Aug. 7, 1973, unless otherwise noted.

§ 1700.1 Definitions.

(a) As used in this part:

(1) Act means the Poison Prevention Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74; 15 U.S.C. 1471-75), enacted December 30, 1970.

(2) Commission means the Consumer Product Safety Commission established by section 4 of the Consumer Product Safety Act (86 Stat. 1210; 15 U.S.C. 2053).

Standards and Protocol, continued

(3) Dietary supplement means any vitamin and/or mineral preparation offered in tablet, capsule, wafer, or other similar uniform unit form; in powder, granule, flake, or liquid form; or in the physical form of a conventional food but which is not a conventional food; and which purports or is represented to be for special dietary use by humans to supplement their diets by increasing the total dietary intake of one or more of the essential vitamins and/or minerals.

(b) Except for the definition of "Secretary," which is obsolete, the definitions given in section 2 of the act are applicable to this part and are repeated herein for convenience as follows:

(1) [Reserved]

(2) Household substance means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is:

(i) A hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));

(ii) A food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(iii) A substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

(3) Package means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household and, for purposes of section 4(a)(2) of the act, also means any outer container or wrapping used in the retail display of any such substance to consumers. "Package" does not include:

(i) Any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; or

(ii) Any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) Special packaging means packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) Labeling means all labels and other written, printed, or graphic matter upon any household substance or its package, or accompanying such substance.

(Pub. L. 92-573, sec. 30(a), 86 Stat. 1231; (15 U.S.C. 2079(a)))
[38 FR 21247, Aug. 7, 1973, as amended at 41 FR 22266, June 2, 1976; 48 FR 57480, Dec. 30, 1983]

Standards and Protocol, continued

§ 1700.2 Authority.

Authority under the Poison Prevention Packaging Act of 1970 is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

§ 1700.3 Establishment of standards for special packaging.

(a) Pursuant to section 3 of the act, the Commission, after consultation with the technical advisory committee provided for by section 6 of the act, may establish by regulation standards for the special packaging of any household substance if the Commission finds:

(1) That the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) That the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing such a standard, the Commission shall consider:

(1) The reasonableness of such standard;

(2) Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) The manufacturing practices of industries affected by the act; and

(4) The nature and use of the household substance.

(c) In the process of establishing such a standard, the Commission shall publish its findings and reasons therefor and shall cite the sections of the act that authorize its action.

(d) In establishing such standards, the Commission shall not prescribe specific packaging designs, product content, package quantity, or labeling except for labeling under section 4(a)(2) of the act. Regarding a household substance for which special packaging is required by regulation, the Commission can prohibit the packaging of such substance in a package which the Commission determines is unnecessarily attractive to children.

(e) Promulgations pursuant to section 3 of the act shall be in accordance with section 5 of the act as to procedure.

Standards and Protocol, continued

§ 1700.4 Effective date of standards.

(a) The FR document promulgating a regulation establishing a child protection packaging standard shall indicate the standard's effective date. Section 9 of the act specifies that the effective date shall not be sooner than 180 days or later than 1 year from the date the standard is promulgated in the Federal Register unless the Commission, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register the reason for such finding, in which case such earlier effective date shall apply.

(b) Upon becoming effective, a child protection packaging standard shall apply only to household substances packaged on and after its effective date.

§ 1700.5 Noncomplying package requirements.

To make household substances that are subject to requirements for special packaging readily available to elderly or handicapped persons who are unable to use those substances in special packaging, section 4(a) of the act authorizes manufacturers and packers to package such substances in noncomplying packaging of a single size provided that complying packaging is also supplied and the noncomplying packages are conspicuously labeled to indicate that they should not be used in households where young children are present. The purpose of this § 1700.5 is to implement section 4(a) of the act by prescribing requirements for the labeling of noncomplying packages.

(a) Labeling statement. (1) The statement “This Package for Households Without Young Children” shall appear conspicuously, and in accordance with all of the requirements of paragraph (a) of this section, on the package of any household substance subject to the special packaging requirements of this part 1700 that is supplied in noncomplying packaging under section 4(a) of the act, unless the package bears the substitute labeling statement in accordance with all of the requirements of paragraph (b) of this section.

(2) The statement required by paragraph (a)(1) of this section shall appear on the principal display panel of the immediate container as well as on the principal display panel of any outer container or wrapping used in the retail display of the substance. If a package bears more than one principal display panel, the required statement shall appear on each principal display panel of the immediate container as well as on each principal display panel of any outer container or wrapping used in the retail display of the substance. The principal display panel is the part of the labeling most likely to be displayed, presented, shown, or examined.

(3) The required labeling statement shall appear within the borderline of a square or rectangle on the principal display panel in conspicuous and easily legible capital letters, shall be in distinct contrast, by typography, layout, color, or embossing, to other matter on the package, and shall appear in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(4) The declaration shall be in letters in type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type-size specifications:

Standards and Protocol, continued

(i) Not less than 1/16 inch in height on packages the principal display panel of which has an area of 7 square inches or less.

(ii) Not less than 3/32 inch in height on packages the principal display panel of which has an area of more than 7 but not more than 15 square inches.

(iii) Not less than 1/8 inch in height on packages the principal display panel of which has an area of more than 15 but not more than 25 square inches.

(iv) Not less than 3/16 inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(v) Not less than 1/4 inch in height on packages the principal display panel of which has an area of more than 100 square inches.

(5)(i) For the purpose of obtaining uniform type size for the required statement for all packages of substantially the same size, the area of the principal display panel is the area of the side or surface that bears the principal display panel, which shall be:

(A) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel, the product of the height times the width of that side.

(B) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference.

(C) In the case of any other shape of container, 40 percent of the total surface of the container; however, if such container presents an obvious principal display (such as the top of a triangular or circular package), the area shall consist of the entire area of such obvious principal display panel.

(ii) In determining the area of the principal display panel exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, the labeling statement required by this section to appear on the principal display panel shall appear within that 40 percent of the circumference most likely to be displayed, presented, shown, or examined.
(b) Substitute labeling statement. If the area of the principal display panel, as determined in accordance with paragraph (a)(5) of this section, is too small to accommodate the statement required by paragraph (a)(1) using the type size required by paragraph (a)(4), the substitute statement “Package Not Child-Resistant” may be used. This substitute statement must comply with all of the requirements for size, placement, and conspicuousness prescribed by paragraph (a) of this section.

[40 FR 4650, Jan. 31, 1975]

Standards and Protocol, continued

§ 1700.14 Substances requiring special packaging.

(a) Substances. The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

(1) Aspirin. Any aspirin-containing preparation for human use in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following:

(i) Effervescent tablets containing aspirin, other than those intended for pediatric use, provided the dry tablet contains not more than 15 percent aspirin and has an oral LD-50 in rats of 5 grams or more per kilogram of body weight.

(ii) Unflavored aspirin-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 15.4 grains of aspirin per unit dose and that contain no other substance subject to the provisions of this section.

(2) Furniture polish. Nonemulsion type liquid furniture polishes containing 10 percent or more of mineral seal oil and/or other petroleum distillates and having a viscosity of less than 100 Saybolt universal seconds at 100 °F., other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (d).

(3) Methyl salicylate. Liquid preparations containing more than 5 percent by weight of methyl salicylate, other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(4) Controlled drugs. Any preparation for human use that consists in whole or in part of any substance subject to control under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) and that is in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(5) Sodium and/or potassium hydroxide. Household substances in dry forms such as granules, powder, and flakes, containing 10 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, and all other household substances containing 2 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(6) Turpentine. Household substances in liquid form containing 10 percent or more by weight of turpentine shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

Standards and Protocol, continued

(7) Kindling and/or illuminating preparations. Prepackaged liquid kindling and/or illuminating preparations, such as cigarette lighter fuel, charcoal lighter fuel, camping equipment fuel, torch fuel, and fuel for decorative or functional lanterns, which contain 10 percent or more by weight of petroleum distillates and have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(8) Methyl alcohol (methanol). Household substances in liquid form containing 4 percent or more by weight of methyl alcohol (methanol), other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(9) Sulfuric acid. Household substances containing 10 percent or more by weight of sulfuric acid, except such substances in wet-cell storage batteries, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(10) Prescription drugs. Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Sublingual dosage forms of nitroglycerin.

(ii) Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams or less.

(iii) Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 grams of the equivalent of erythromycin.

(iv) Cyclically administered oral contraceptives in manufacturers' mnemonic (memory-aid) dispenser packages that rely solely upon the activity of one or more progestogen or estrogen substances.

(v) Anhydrous cholestyramine in powder form.

(vi) All unit dose forms of potassium supplements, including individually-wrapped effervescent tablets, unit dose vials of liquid potassium, and powdered potassium in unit-dose packets, containing not more than 50 milliequivalents of potassium per unit dose.

(vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package or not more than a concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to this § 1700.14(a)(10).

(viii) Betamethasone tablets packaged in manufacturers' dispenser packages, containing no more than 12.6 milligrams betamethasone.

(ix) Pancrelipase preparations in tablet, capsule, or powder form and containing no other substances subject to this § 1700.14(a)(10).

Standards and Protocol, continued

(x) Prednisone in tablet form, when dispensed in packages containing no more than 105 mg. of the drug, and containing no other substances subject to this § 1700.14(a)(10).

(xi)-(xii) [Reserved]

(xiii) Mebendazole in tablet form in packages containing not more than 600 mg. of the drug, and containing no other substance subject to the provisions of this section.

(xiv) Methylprednisolone in tablet form in packages containing not more than 84 mg of the drug and containing no other substance subject to the provisions of this section.

(xv) Colestipol in powder form in packages containing not more than 5 grams of the drug and containing no other substance subject to the provisions of this section.

(xvi) Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin.

(xvii) Conjugated Estrogens Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 32.0 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).

(xviii) Norethindrone Acetate Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 50 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).

(xix) Medroxyprogesterone acetate tablets.

(xx) Sacrosidase (sucrase) preparations in a solution of glycerol and water.

(xxi) Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.

(xxii) Colesevelam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug.

(xxiii) Sevelamer carbonate in powder form in packages containing not more than 2.4 grams of the drug.

(11) Ethylene glycol. Household substances in liquid form containing 10 percent or more by weight of ethylene glycol packaged on or after June 1, 1974, except those articles exempted by 16 CFR 1500.83, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

Standards and Protocol, continued

(12) Iron-containing drugs. With the exception of: (i) Animal feeds used as vehicles for the administration of drugs, and (ii) those preparations in which iron is present solely as a colorant, noninjectable animal and human drugs providing iron for therapeutic or prophylactic purposes, and containing a total amount of elemental iron, from any source, in a single package, equivalent to 250 mg or more elemental iron in a concentration of 0.025 percent or more on a weight to volume basis for liquids and 0.025 percent or more on a weight to volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(13) Dietary supplements containing iron. Dietary supplements, as defined in § 1700.1(a)(3), that contain an equivalent of 250 mg or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Preparations in which iron is present solely as a colorant; and

(ii) Powdered preparations with no more than the equivalent of 0.12 percent weight-to-weight elemental iron.

(14) [Reserved]

(15) Solvents for paint or other similar surface-coating material. Prepackaged liquid solvents (such as removers, thinners, brush cleaners, etc.) for paints or other similar surface-coating materials (such as varnishes and lacquers), that contain 10 percent or more by weight of benzene (also known as benzol), toluene (also known as toluol), xylene (also known as xylol), petroleum distillates (such as gasoline, kerosene, mineral seal oil, mineral spirits, naphtha, and Stoddard solvent, etc.), or combinations thereof, and that have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(16) Acetaminophen. Preparations for human use in a dosage form intended for oral administration and containing in a single package a total of more than one gram acetaminophen shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following—

(i) Effervescent tablets or granules containing acetaminophen, provided the dry tablet or granules contain less than 15 percent acetaminophen, the tablet or granules have an oral LD-50 of 5 grams or greater per kilogram of body weight, and the tablet or granules contain no other substance subject to the provisions of this section.

(ii) Unflavored acetaminophen-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 13 grains of acetaminophen per unit dose and that contain no other substance subject to this § 1700.14(a).

Standards and Protocol, continued

(17) Diphenhydramine. Preparations for human use in a dosage form intended for oral administration and containing more than the equivalent of 66 mg diphenhydramine base in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), if packaged on or after February 11, 1985.

(18) Glue removers containing acetonitrile. Household glue removers in a liquid form containing more than 500 mg of acetonitrile in a single container.

(19) Permanent wave neutralizers containing sodium bromate or potassium bromate. Home permanent wave neutralizers, in a liquid form, containing in single container more than 600 mg of sodium bromate or more than 50 mg of potassium bromate.

(20) Ibuprofen. Ibuprofen preparations for human use in a dosage form intended for oral administration and containing one gram (1,000 mg) or more of ibuprofen in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(21) Loperamide. Preparations for human use in a dosage form intended for oral administration and containing more than 0.045 mg of loperamide in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(22) Mouthwash. Except as provided in the following sentence, mouthwash preparations for human use and containing 3 g or more of ethanol in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c). Mouthwash products with nonremovable pump dispensers that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single unit are exempt from this requirement. The term “mouthwash” includes liquid products that are variously called mouthwashes, mouthrinses, oral antiseptics, gargles, fluoride rinses, anti-plaque rinses, and breath fresheners. It does not include throat sprays or aerosol breath fresheners.

(23) Lidocaine. Products containing more than 5.0 mg of lidocaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(24) Dibucaine. Products containing more than 0.5 mg of dibucaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(25) Naproxen. Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(26) Ketoprofen. Ketoprofen preparations for human use and containing more than 50 mg of ketoprofen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b) and (c).

Standards and Protocol, continued

(27) Fluoride. Household substances containing more than the equivalent of 50 milligrams of elemental fluoride per package and more than the equivalent of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c).

(28) Minoxidil. Minoxidil preparations for human use and containing more than 14 mg of minoxidil in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c). Any applicator packaged with the minoxidil preparation and which it is reasonable to expect may be used to replace the original closure shall also comply with the provisions of § 1700.15(a), (b) and (c).

(29)Methacrylic acid. Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: (i) the methacrylic acid is contained by the absorbent material so that no free liquid is within the device, and (ii) under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

(30) Over-the-Counter Drug Products. (i) Any over-the-counter (OTC) drug product in a dosage form intended for oral administration that contains any active ingredient that was previously available for oral administration only by prescription, and thus was required by paragraph (a)(10) of this section to be in special packaging, shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c). This requirement applies whether or not the amount of that active ingredient in the OTC drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply if the OTC drug product contains only active ingredients of any oral drug product or products approved for OTC marketing based on an application for OTC marketing submitted to the Food and Drug Administration (FDA) by any entity before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this § 1700.14 otherwise applicable to an OTC drug product remains in effect.

(ii) For purposes of this paragraph (30), active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of humans; and drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance (active ingredient), generally, but not necessarily, in association with one or more other ingredients. (These terms are intended to have the meanings assigned to them in the regulations of the Food and Drug Administration appearing at 21 CFR 201.66 (2001) and 21 CFR 314.3 (2000), respectively.)

(31) Hazardous substances containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are hazardous substances as defined in the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261(f)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100 °F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

Standards and Protocol, continued

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols, or pump-or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Writing markers and ballpoint pens exempted from labeling requirements under the FHSA by 16 CFR 1500.83.

(iii) Products from which the liquid cannot flow freely, including but not limited to paint markers and battery terminal cleaners. For purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

(32) Drugs and cosmetics containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are drugs or cosmetics as defined in the Federal Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. 321(a)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100 °F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols, or pump-or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Products from which the liquid cannot flow freely, including but not limited to makeup removal pads. For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

(b) Sample packages. (1) The manufacturer or packer of any of the substances listed under paragraph (a) of this section as substances requiring special packaging shall provide the Commission with a sample of each type of special packaging, as well as the labeling for each size product that will be packaged in special packaging and the labeling for any noncomplying package. Sample packages and labeling should be sent to the Consumer Product Safety Commission, Office of Compliance, 4330 East West Highway, Washington, DC 20207.

(2) Sample packages should be submitted without contents when such contents are unnecessary for demonstrating the effectiveness of the packaging.

(3) Any sample packages containing drugs listed under paragraph (a) of this section shall be sent by registered mail.

(4) As used in paragraph (b)(1) of this section, the term manufacturer or packer does not include pharmacists and other individuals who dispense, at the retail or user level, drugs listed under paragraph (a) of this section as requiring special packaging.

Standards and Protocol, continued

(c) Applicability. Special packaging standards for drugs listed under paragraph (a) of this section shall be in addition to any packaging requirements of the Federal Food, Drug, and Cosmetic Act or regulations promulgated thereunder or of any official compendia recognized by that act.

(Pub. L. 91-601, secs. 2(4), 3, 5, 85 Stat. 1670-72; 15 U.S.C. 1471(4), 1472, 1474; Pub. L. 92-573, 86 Stat. 1231; 15 U.S.C. 2079(a)) [38 FR 21247, Aug. 7, 1973]

§ 1700.15 Poison prevention packaging standards.

To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commission has determined that packaging designed and constructed to meet the following standards shall be regarded as "special packaging" within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with § 1700.14.

(a) General requirements. The special packaging must continue to function with the effectiveness specifications set forth in paragraph (b) of this section when in actual contact with the substance contained therein. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging. The special packaging must also continue to function with the effectiveness specifications set forth in paragraph (b) of this section for the number of openings and closings customary for its size and contents. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other such relevant factors which establish that, for the duration of normal use, the effectiveness specifications of the packaging would not be expected to lessen.

(b) Effectiveness specifications. Special packaging, tested by the method described in § 1700.20, shall meet the following specifications:

(1) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(2) Ease of adult opening—(i) Senior-adult test. Except for products specified in paragraph (b)(2)(ii) of this section, special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test of § 1700.20(a)(3).

(ii) Younger-adult test—(A) When applicable. Products that must be in aerosol form and products that require metal containers, under the criteria specified below, shall have an effectiveness of not less than 90% for the younger-adult test of § 1700.20(a)(4). The senior-adult panel test of § 1700.20(a)(3) does not apply to these products. For the purposes of this paragraph, metal containers are those that have both a metal package and a recloseable metal closure, and aerosol products are self-contained pressurized products.

Standards and Protocol, continued

(B) Determination of need for metal or aerosol container—(1) Criteria. A product will be deemed to require metal containers or aerosol form only if:

(i) No other packaging type would comply with other state or Federal regulations,

(ii) No other packaging can reasonably be used for the product's intended application,

(iii) No other packaging or closure material would be compatible with the substance,

(iv) No other suitable packaging type would provide adequate shelf-life for the product's intended use, or

(v) Any other reason clearly demonstrates that such packaging is required.

(2) Presumption. In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product, or another product of identical composition, has previously been marketed in packaging using either a nonmetal package or a nonmetal closure.

(3) Justification. A manufacturer or packager of a product that is in a metal container or aerosol form that the manufacturer or packager contends is not required to comply with the SAUE requirements of § 1700.20(a)(3) shall provide, if requested by the Commission's staff, a written explanation of why the product must have a metal container or be an aerosol. Manufacturers and packagers who wish to do so voluntarily may submit to the Commission's Office of Compliance a rationale for why their product must be in metal containers or be an aerosol. In such cases, the staff will reply to the manufacturer or packager, if requested, stating the staff's views on the adequacy of the rationale.

(c) Reuse of special packaging. Special packaging for substances subject to the provisions of this paragraph shall not be reused.

(d) Restricted flow. Special packaging subject to the provisions of this paragraph shall be special packaging from which the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once.

(Secs. 2(4), 3, 5, 84 Stat. 1670-72; 15 U.S.C. 1471(4), 1472, 1474)

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37734, July 21, 1995]

§ 1700.20 Testing procedure for special packaging.

(a) Test protocols—(1) General requirements—(i) Requirements for packaging. As specified in § 1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this § 1700.20.

Standards and Protocol, continued

(ii) Condition of packages to be tested—(A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies:

(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.

(B) Reclosable packages—adult tests. In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to “take a set.” If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) Child test—(i) Test subjects—(A) Selection criteria. Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20% of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40% of the children in each group shall be of age 45-48 months, and 30% of the children in each group shall be of age 49-51 months. The children's ages in months shall be calculated as follows:

(1) Arrange the birth date and test date by the numerical designations for month, day, and year (e.g., test date: 8/3/1990; birth date: 6/23/1986).

(2) Subtract the month, day, and year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days. (e.g.,

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this value to the number of months that was obtained when the birth date was subtracted from the test date (i.e., 4 × 12 = 48; 48 + 2 = 50). This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

Standards and Protocol, continued

(4) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is −16 or less, subtract 1 month. If the number of days is between −15 and +15 inclusive, no change is made in the number of months. Thus, for the example given above, the number of days is −20, and the number of months is therefore 50 − 1 = 49 months.

(B) Gender distribution. The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. A parent or guardian of each child shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) Test failures. A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound (11.4 kg) child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) Sequential test. The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30% of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in table 1 are cumulative.

Standards and Protocol, continued

Table 1—Number of Openings: Acceptance (Pass), Continue Testing, and Rejection (Fail) Criteria for the First 5 Minutes and the Full 10 Minutes of the Children's Protocol Test

Test Panel	Cumulative number of children	Package Openings					
		First 5 Minutes			Full 10 Minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0-3	4-10	11+	0-5	6-14	15+
2	100	4-10	11-18	19+	6-15	16-24	25+
3	150	11-18	19-25	26+	16-25	26-34	35+
4	200	19-30	--	31+	26-40	--	41+

(iv) Test procedures. The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children, for example, their customary nursery school or regular kindergarten. No child shall test more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

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1. Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials (e.g., the closure liner) to “take a set.” Application torques must be recorded in the test report.

2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

3. Reclosable packages shall be opened and properly resecured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and resecuring shall not be done in the presence of the children. (In the adult-resecuring test, the tester must not open and resecure the package prior to the test.) If multiple openings/resecurings are to be used, each of four (4) testers shall open and properly resecure one fourth of the packages once and then shall open and properly resecure each package a second, third, fourth, through tenth (or other specified number) time, in the same sequence as the first opening and resecuring. The packages shall not be opened and resecured again prior to testing. The name of each tester and the package numbers that he/she opens and resecures shall be recorded and reported. It is not necessary for the testers to protocol test the packages that they opened and resecured.

Standards and Protocol, continued

4. The children shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.

5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.

6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.

7. The tester shall talk to the children to make them feel at ease.

8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.

9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.
10. The tester shall use a stopwatch(s) or other timing devices to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.

11. To begin the test, the tester shall hand the children identical packages and say, “PLEASE TRY TO OPEN THIS FOR ME.”

12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversation with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., “please try to open the package”).

14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).

15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the final results.

16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.

17. A child shall not be allowed to try to open the other child's package.

Standards and Protocol, continued

18. If a child opens his/her package, the tester shall say, “THANK YOU,” take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.

19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate “demo” package shall be used for the demonstration.

20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.

21. The tester shall say, “WATCH ME OPEN MY PACKAGE.”

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, “NOW YOU TRY TO OPEN YOUR PACKAGES.”

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, “YOU CAN USE YOUR TEETH IF YOU WANT TO.” This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, “THANK YOU FOR HELPING.” If children were told that they could use their teeth, the tester shall say, “I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN” In addition, the tester shall say, “NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK.”

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

Standards and Protocol, continued

(3) Senior-adult panel—(i) Test subjects. Use a group of 100 senior adults. Not more than 24% of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability.

(ii) Screening procedures. Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or "special") closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm±18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce±1/2 ounce for the CT-type closure and 8 drams±4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.

(iv) Test procedures. The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

Test Instructions for Senior Test

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability that would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Examples of the forms used by the Commission staff for testing are shown at § 1700.20(d). Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

Standards and Protocol, continued

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the package are the only exceptions.

6. To begin the first 5-minute test period, the tester says, “I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP.” (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, “PLEASE OPEN THIS PACKAGE ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, “PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.” After the participant opens the package, the tester says, “PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resecuring times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, “ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?” If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, “THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, “PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.” After the participant opens the package, the tester says, “PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

Standards and Protocol, continued

12. After the 1-minute test, or when the participant has opened and finished closing the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, “ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?” If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, “PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE.” The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, “PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE.” The time to open and resecure, or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-seniors panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

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 resecuring 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 resecuring 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.

(b) The standards published as regulations issued for the purpose of designating particular substances as being subject to the requirements for special packaging under the act will stipulate the percent of child-resistant effectiveness and adult-use effectiveness required for each and, where appropriate, will include any other conditions deemed necessary and provided for in the act.

Standards and Protocol, continued

(c) It is recommended that manufacturers of special packaging, or producers of substances subject to regulations issued pursuant to the act, submit to the Commission summaries of data resulting from tests conducted in accordance with this protocol.

(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 photographs(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.

Standards and Protocol, continued

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-resecuring test instructions. CPSC will use the adult-resecuring test where an objective determination (e.g., visual or mechanical) that a package is properly resecured cannot be made.

The adult-resecuring test is performed as follows:

Adult-Resecuring 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 resecured 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 resecured by adults shall be tested by children according to the child-test procedures to determine if the packages have been properly resecured. The packages are given to the children without being opened or resecured again for any purpose.

Standards and Protocol, continued

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

a. Adult use effectiveness.

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

Standards and Protocol, continued

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 resecured; packages opened by males and by females; and packages resecured 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 resecuring times and standard deviation for total resecurings, total resecurings by females and total resecurings 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.

Standards and Protocol, continued

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

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970. The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened and properly closed by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

1. I will give you a package and ask you to read the instructions and open and properly close the package.

2. I will then give you an identical package, and ask you to open and properly close it.

3. I may ask you to open some other types of packages.

4. The packages may be empty or they may contain a product.

5. I will ask you whether you think the child-resistant package was easy or hard to use.

Standards and Protocol, continued

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.

Birthdate
Signature
Date
Zip Code

Office Use

Site:
Sample Number:
Test Number:
Package Number:

2. Unit-dose packages.

[Testing Organization's Letterhead]

Unit Dose Child-Resistant Package Testing

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970.

The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Standards and Protocol, continued

Description of the Test

1. I will give you a package and ask you to read the instructions, open one unit, and remove the contents.

2. I will then give you an identical package, and ask you to open one unit and remove the contents.

3. I may ask you to open some other types of packages.

4. I will ask you whether you think the child-resistant package was easy or hard to use.

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.

Birthdate
Signature
Date
Zip Code

Office Use

Site:
Sample Number:
Test Number:
Package Number:

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37735, 37738, July 22, 1995]

TREAD GLOBAL
International Product Sourcing and Development

POISON PREVENTION PACKAGING

Test Report for

SECURESACK

MAY 25, 2018

Conducted For

COLOR AD PACKAGING, LTD.

ColorAd Packaging Ltd.

TREAD GLOBAL
International Product Sourcing and Development

999 18th Street, Suite 3000, Denver, CO 80202
www.TreadGlobal.com Phone (303) 993-8943

MAY 25, 2018

Chip Batten, CEO
Color Ad Packaging, Ltd.
200 Beghin Ave.
Winnipeg, MB, Canada R2J 3W2

Dear Mr. Batten:

Attached is our report of the Poison Prevention Packaging testing that has been completed for your product, the SecureSack.

Your product has been evaluated using the Consumer Product Safety Commission's protocol and standards. The test results show that SecureSack fulfills the requirements for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700.

In the testing of the SecureSack two senior adults failed to open the package, a 98% effectiveness rate. None of the children were able to open the package, a child-resistant effectiveness of 100%.

I look forward to reviewing your report results with you at your convenience.

Sincerely,

Jeremiah Buck
Director of Product Development
Tread Global, Inc.

Participating Member ASTM, #1747717
Member of Child-Resistant Packaging Sub-Committee

TREAD GLOBAL, INC.
POISON PREVENTION PACKAGING TEST REPORT FOR
THE SECURESACK
MAY 25, 2018

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TREAD GLOBAL
International Product Sourcing and Development

999 18th Street, Suite 3000, Denver, CO 80202
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REPORT SYNOPSIS

MAY 25, 2018

Report issued to: Chip Batten, CEO
Color Ad Packaging, Ltd.
200 Beghin Ave.
Winnipeg, MB, Canada R2J 3W2

Product tested: SecureSack (3.62" x 5.86" x 1.5")

Manufacturer: Color Ad Packaging, Ltd.

Testing dates: Testing began April 30, 2018
Testing ended May 16, 2018

Objective

Color Ad Packaging, Ltd. submitted the SecureSack (3.62" x 5.86" x 1.5") for analysis to determine if the package is in compliance with the Consumer Product Safety Commission's (CPSC) protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700, including Part 1700.15 (1995) and Part 1700.20 (1995). (see Addendum)

Procedures

The protocols for the evaluation of packaging for poison prevention (CFR Title 16, Part 1700) were strictly adhered to for this study, unless otherwise documented.

Participants

In the course of this study, 50 children (42 to 51 months of age) and 100 senior adults (50 to 70 years old, 70% female) were employed.

Results

Results of this study indicate that the SecureSack (3.62" x 5.86" x 1.5") meets the standards for Poison Prevention Packaging as required by CFR Title 16, Part 1700.

Tread Global, Inc. is recognized in the field of consumer product testing and development, and has been employed by Color Ad Packaging, Ltd. to ascertain if their product, the SecureSack (3.62" x 5.86" x 1.5"), fulfills the Consumer Product Safety Commission's (CPSC) standards for Poison Prevention Packaging as set forth in CFR Title 16, Part 1700.

Tread Global, Inc. is an independent product development company who also provides various testing services for a wide range of consumer products. Affordable Testing Solutions Limited, administrators of this test, has years of extensive experience performing tests for consumer product safety, and specializes in child related safety testing as required in CFR Title 16, Part 1700. Testing was performed according to CPSC protocol.

Tread Global, Inc. utilizes standard operating procedures along with quality assurance programs consistent with the protocols acknowledged and supported by the Consumer Product Safety Commission.

“Child-resistant packaging” means packaging that is designed and constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

In the course of this evaluation, the packaging was tested with participants consisting of 100 senior adults (50 to 70 year-olds, 70% female) and 50 children (42 to 51 months of age, evenly distributed by gender). The data derived from the study was compiled and reviewed to determine whether the packaging met the cited standards for Poison Prevention Packaging presented herein. (See Tables 1 and 2, and Testing Results Summary)

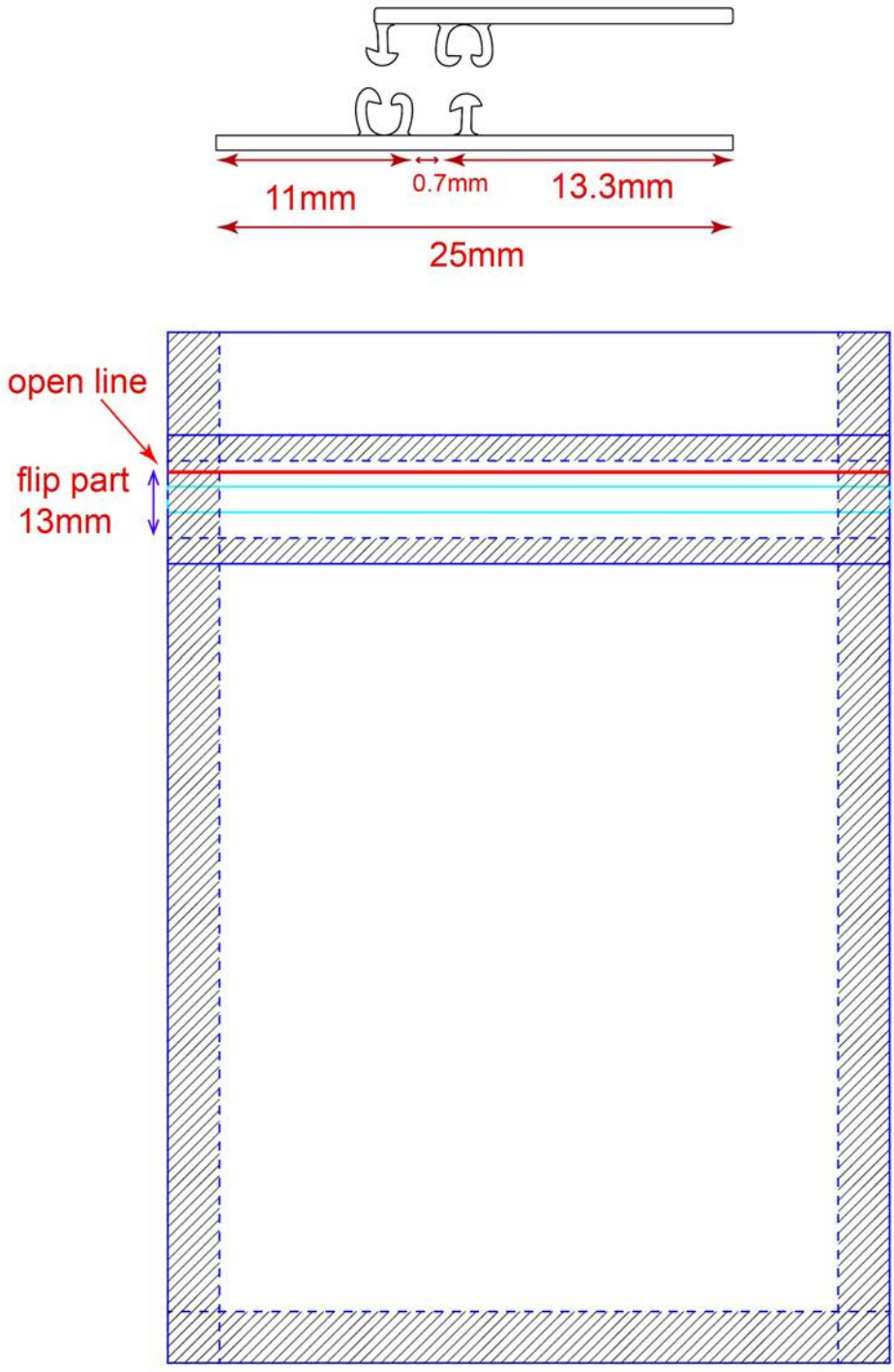
The Package

The package submitted for testing was the SecureSack, a package with dimensions of 3.62" x 5.86" with a 1.5" bottom gusset. The package has a white exterior and silver interior, is heat sealed on three sides with a double press and seal zipper at the top. The zipper is opened by pulling a flap on one side of the package and the top opening of the opposite side. (See photos below.) Color Ad Packaging, Ltd. reports that the package is constructed of a film of polyethylene (PE), a thermoplastic, and polyethylene terephthalate (PET), a thermoplastic polymer resin; the zipper is constructed of polyethylene (PE), a thermoplastic. Graphic opening instructions are printed below the zipper (See photo below.) This configuration is referred to in this report as the "SecureSack", "the package" or "the container".

The SecureSack is intended to contain various products that require child-resistant packaging.

For purposes of this test, each participant was given a new package that had never been opened. All of the units were empty. The Test Administrators asked all adult participants to open and reclose the package properly; the children were asked to open the package.

Continued



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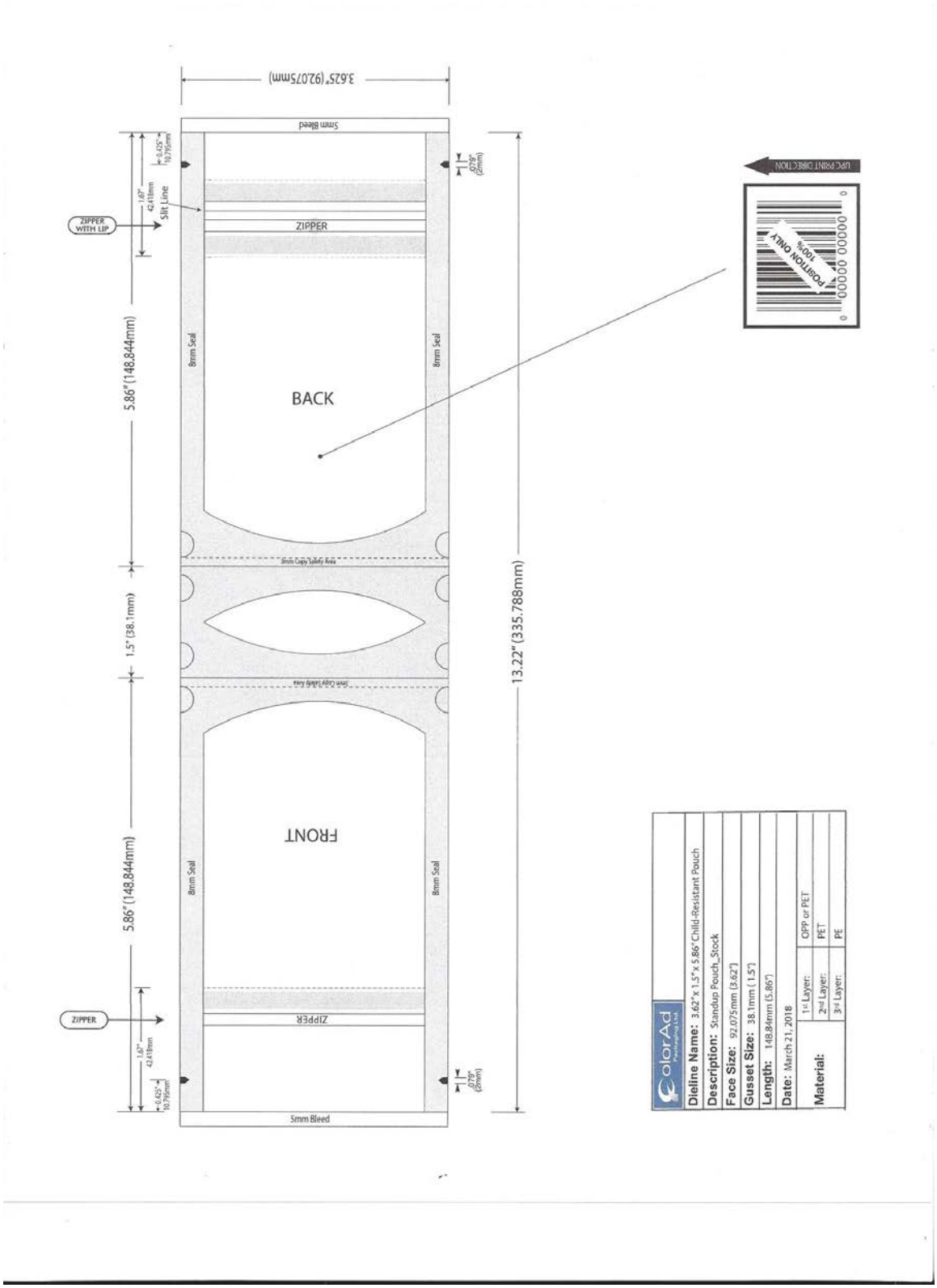

3.625" (92.075mm)
5mm Bleed
ZIPPER WITH LIP
Slit Line
ZIPPER
8mm Seal
8mm Seal
BACK
5.86" (148.844mm)
1.5" (38.1mm)
FRONT
5.86" (148.844mm)
13.22" (335.788mm)
ZIPPER
ZIPPER
5mm Bleed
UPC PRINT DIRECTION
POSITION ONLY
100%
Dieline Name: 3.62"x 1.5"x 5.86" Child-Resistant Pouch
Description: Standup Pouch_Stock
Face Size: 92.075mm (3.62")
Gusset Size: 38.1mm (1.5")
Length: 148.84mm (5.86")
Date: March 21, 2018
Material:
1st Layer: OPP or PET
2nd Layer: PET
3rd Layer: PE

Continued

Participants

In the children's testing phase, 50 children were employed between the ages of 42 and 51 months and were divided into three age groups (42-44, 45-48, and 49-51 months, evenly distributed by gender).

In the senior adult's testing phase, 100 senior adults were employed with ages ranging from 50 to 70 years of age, divided into three age groups (50-54, 55-59, and 60-70 years of age, 70% female).

Test Administrators

Test Administrators were instructed to conduct the evaluation of the packaging in strict accordance with the standards and protocols required by the CFR Title 16, Part 1700, unless otherwise documented. The Test Administrators asked all adult participants to open and reclose the package properly; the children were asked to open the package.

Materials

The SecureSack is manufactured by Color Ad Packaging, Ltd.

The package is constructed of a film of polyethylene (PE), a thermoplastic, and polyethylene terephthalate (PET), a thermoplastic polymer resin; used for its low reactivity at room temperature, flexibility, versatile chemical, gas and water resistance, strength and impact-resistance, as well as being lightweight. The zipper is constructed of polyethylene (PE), a thermoplastic used for its low reactivity at room temperature, flexibility, and versatile chemical and water resistance.

Individual results of this study appear in the Data Evaluation section of this report. The tables presented represent a compilation of all data obtained during the study. For clarity in presentation and discussion of this information, the following features will be used as the major points of discussion:

* Child-resistant effectiveness
* Senior adult use effectiveness (SAUE)
* Code Requirements

Child-Resistant Effectiveness

Results of the children's testing appear in Table 1 of this report. This Table demonstrates that none of the children were able to open the SecureSack during the entire ten minute testing, a 0% failure rate and a child-resistant effectiveness of 100%, exceeding the CFR Title 16, Part 1700 minimum requirements.

Senior Adult Use Effectiveness

Results of the senior adult's testing appear in Table 2 of this report. This Table shows that two of the senior adult participants had failures in the attempt to open the SecureSack. The SAUE was calculated at 98%, exceeding the CFR Title 16, Part 1700 minimum requirements.

Code Requirements

The results of the testing of the SecureSack show that the package meets the Consumer Product Safety Commission's (CPSC) protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700.

Test Results and Evaluation

Table 1

**Summary of Package Opening Test Results for the SecureSack
Evaluated by Children 42 to 51 Months of Age
For Child-Resistant Effectiveness**

				Successful Package Openings				
				First Test Period		Second Test Period		
Age in Months	Males	Females	Total	Males	Females	Males	Females	Total
42-44	7	8	15	0	0	0	0	0
45-48	10	10	20	0	0	0	0	0
49-51	8	7	15	0	0	0	0	0
Total	**25**	**25**	**50**	**0**	**0**	**0**	**0**	**0**

Per CPSC protocol, children are allowed up to five minutes to open the package in each of two testing periods.

A test is considered failed when any child opens the special packaging or gains access to its contents within the time allotted.

Times for failed tests are listed as “minutes : seconds”.

Test Results and Evaluation, continued

Children's Data, 42-51 Months, SecureSack

Test #	Age in Months	Gender	Pass/ Failed Time	Test Site	Tester
1	43	M	Pass	12	4
2	42	M	Pass	7	2
3	44	M	Pass	20	3
4	44	M	Pass	4	2
5	42	M	Pass	5	1
6	43	M	Pass	2	3
7	44	M	Pass	3	1
8	43	F	Pass	12	4
9	42	F	Pass	9	4
10	42	F	Pass	7	2
11	42	F	Pass	6	6
12	44	F	Pass	5	1
13	44	F	Pass	8	6
14	43	F	Pass	21	5
15	42	F	Pass	1	3
16	46	M	Pass	12	4
17	48	M	Pass	12	5
18	47	M	Pass	7	2
19	47	M	Pass	20	3
20	45	M	Pass	2	3
21	46	M	Pass	5	1
22	48	M	Pass	5	1
23	45	M	Pass	1	3
24	46	M	Pass	10	5
25	47	M	Pass	10	5

Test Results and Evaluation, continued

Children's Data, 42-51 Months, SecureSack, continued

Test #	Age in Months	Gender	Pass/ Failed Time	Test Site	Tester
26	46	F	Pass	12	4
27	47	F	Pass	9	4
28	45	F	Pass	7	2
29	48	F	Pass	20	3
30	48	F	Pass	4	2
31	46	F	Pass	5	1
32	45	F	Pass	8	6
33	46	F	Pass	8	6
34	45	F	Pass	11	5
35	47	F	Pass	10	5
36	51	M	Pass	12	4
37	50	M	Pass	7	2
38	51	M	Pass	6	6
39	49	M	Pass	4	2
40	49	M	Pass	5	1
41	51	M	Pass	8	6
42	50	M	Pass	10	5
43	49	M	Pass	1	2
44	51	F	Pass	12	5
45	50	F	Pass	9	4
46	50	F	Pass	20	3
47	50	F	Pass	5	1
48	49	F	Pass	8	6
49	51	F	Pass	21	5
50	51	F	Pass	3	2

Test Results and Evaluation, continued

Children's Data, 42-51 Months, SecureSack, continued

Test Results and Evaluation, continued

Table 2

Summary of Package Opening Test Results for SecureSack
Evaluated by Senior Adults Age 50-70 Years
For Senior Adult Use Effectiveness

		Successful Package Openings		
Age and Gender	**Participants Tested**	**First Opening**	**Second Opening**	**Total Failures**
50-54 years old:				
Females	18	18	6	0
Males	7	7	1	0
Subtotal	**25**	**25**	**7**	**0**
55-59 years old:				
Females	17	16	5	1
Males	8	8	2	0
Subtotal	**25**	**24**	**7**	**1**
60-70 years old:				
Females	35	34	12	1
Males	15	15	6	0
Subtotal	**50**	**49**	**18**	**1**
Total	**100**	**98**	**32**	**2**

Per CPSC protocol, in order to pass the first testing period, participants are allowed up to five minutes to open and reclose the package. In order to pass the second testing period, participants are allowed one minute to open and reclose the package. Participants who opened and reclosed the package in under one minute in the first testing period were not tested a second time.

A senior adult test is considered failed when any adult is unable to open and reclose the package within five minutes during the first test period, or is unable to open and reclose the package within one minute during the second test period.

In the following tables, adults were asked to rate the degree of difficulty of opening the package using the terms "Easy, Medium, or Hard".

Times are recorded as "minutes : seconds".

Test Results and Evaluation, continued

Senior Adult Data, 50-54 Years, SecureSack

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
1	50	M	0:47	0:04	n/a	n/a	Pass	Easy	15	2
2	53	M	0:23	0:06	n/a	n/a	Pass	Easy	16	1
3	52	M	0:52	0:04	n/a	n/a	Pass	Medium	17	2
4	51	M	0:18	0:03	n/a	n/a	Pass	Easy	11	6
5	51	M	1:06	0:07	0:04	0:06	Pass	Easy	19	6
6	54	M	0:42	0:05	n/a	n/a	Pass	Easy	18	1
7	53	M	0:30	0:06	n/a	n/a	Pass	Easy	17	3
8	54	F	0:45	0:03	n/a	n/a	Pass	Easy	12	5
9	53	F	1:12	0:05	0:08	0:07	Pass	Medium	14	6
10	52	F	0:34	0:06	n/a	n/a	Pass	Easy	14	6
11	50	F	0:20	0:04	n/a	n/a	Pass	Easy	15	2
12	51	F	0:46	0:05	n/a	n/a	Pass	Easy	15	2
13	52	F	0:57	0:06	0:05	0:04	Pass	Easy	15	2
14	53	F	0:39	0:05	n/a	n/a	Pass	Easy	16	6
15	54	F	0:22	0:04	n/a	n/a	Pass	Easy	16	1
16	51	F	0:49	0:06	n/a	n/a	Pass	Easy	16	1
17	53	F	1:20	0:04	0:13	0:05	Pass	Medium	17	2
18	50	F	0:35	0:06	n/a	n/a	Pass	Easy	17	2
19	54	F	0:28	0:04	n/a	n/a	Pass	Easy	1	2
20	53	F	2:05	0:05	0:05	0:04	Pass	Easy	19	6
21	52	F	0:36	0:07	n/a	n/a	Pass	Easy	2	6
22	54	F	1:15	0:05	0:10	0:06	Pass	Medium	1	3
23	51	F	0:52	0:04	n/a	n/a	Pass	Medium	18	6
24	50	F	0:19	0:05	n/a	n/a	Pass	Easy	18	1
25	51	F	1:28	0:08	0:04	0:05	Pass	Easy	2	3

Test Results and Evaluation, continued

Senior Adult Data, 55-59 Years, SecureSack

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
26	58	M	0:28	0:04	n/a	n/a	Pass	Easy	13	4
27	57	M	0:54	0:05	n/a	n/a	Pass	Easy	15	2
28	58	M	0:39	0:07	n/a	n/a	Pass	Easy	16	1
29	55	M	0:50	0:04	n/a	n/a	Pass	Easy	19	6
30	56	M	1:13	0:06	0:03	0:05	Pass	Easy	2	1
31	58	M	0:51	0:04	n/a	n/a	Pass	Easy	18	6
32	57	M	0:17	0:05	n/a	n/a	Pass	Easy	18	1
33	56	M	1:24	0:04	0:07	0:08	Pass	Medium	17	3
34	59	F	0:54	0:05	n/a	n/a	Pass	Easy	13	4
35	55	F	0:43	n/a	n/a	n/a	Fail	Hard	12	5
36	58	F	0:50	0:05	n/a	n/a	Pass	Easy	14	6
37	57	F	1:02	0:06	0:04	0:05	Pass	Easy	15	2
38	55	F	0:48	0:08	n/a	n/a	Pass	Easy	15	2
39	59	F	1:30	0:05	0:26	0:07	Pass	Medium	16	1
40	55	F	0:24	0:03	n/a	n/a	Pass	Easy	16	1
41	58	F	0:33	0:05	n/a	n/a	Pass	Easy	16	6
42	56	F	0:59	0:08	0:05	0:10	Pass	Easy	17	2
43	55	F	0:47	0:05	n/a	n/a	Pass	Easy	17	2
44	59	F	0:53	0:06	n/a	n/a	Pass	Easy	17	2
45	57	F	2:07	0:04	0:08	0:05	Pass	Medium	2	6
46	57	F	0:45	0:04	n/a	n/a	Pass	Easy	1	3
47	55	F	0:28	0:03	n/a	n/a	Pass	Easy	18	1
48	59	F	0:30	0:05	n/a	n/a	Pass	Easy	18	1
49	56	F	1:04	0:05	0:07	0:04	Pass	Medium	18	6
50	56	F	0:27	0:04	n/a	n/a	Pass	Easy	17	3

Test Results and Evaluation, continued

Senior Adult Data, 60-70 Years, SecureSack

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
51	62	M	1:12	0:06	0:04	0:05	Pass	Easy	12	5
52	64	M	0:44	0:05	n/a	n/a	Pass	Easy	14	6
53	69	M	0:38	0:06	n/a	n/a	Pass	Easy	15	2
54	67	M	1:05	0:04	0:04	0:07	Pass	Easy	15	2
55	60	M	0:19	0:04	n/a	n/a	Pass	Easy	1	2
56	61	M	0:30	0:05	n/a	n/a	Pass	Easy	16	1
57	64	M	1:16	0:06	0:07	0:05	Pass	Medium	16	1
58	67	M	0:31	0:03	n/a	n/a	Pass	Easy	19	6
59	62	M	1:33	0:04	0:18	0:06	Pass	Medium	2	1
60	60	M	1:03	0:05	0:05	0:07	Pass	Easy	18	1
61	62	M	0:42	0:06	n/a	n/a	Pass	Easy	18	6
62	65	M	0:50	0:07	n/a	n/a	Pass	Easy	18	6
63	63	M	1:54	0:05	0:06	0:06	Pass	Medium	17	3
64	66	M	0:39	0:06	n/a	n/a	Pass	Easy	17	3
65	61	M	0:51	0:03	n/a	n/a	Pass	Medium	17	3
66	64	F	0:37	0:05	n/a	n/a	Pass	Easy	13	4
67	69	F	1:09	0:06	0:04	0:05	Pass	Easy	13	4
68	68	F	0:40	0:04	n/a	n/a	Pass	Easy	14	6
69	65	F	0:32	0:08	n/a	n/a	Pass	Easy	14	6
70	61	F	0:16	0:05	n/a	n/a	Pass	Easy	14	6
71	66	F	0:54	0:04	n/a	n/a	Pass	Easy	14	6
72	70	F	1:33	0:08	0:15	0:07	Pass	Medium	15	2
73	68	F	0:30	0:04	n/a	n/a	Pass	Easy	15	2
74	65	F	0:52	0:07	n/a	n/a	Pass	Easy	15	2
75	69	F	0:58	0:06	0:08	0:04	Pass	Easy	15	2

Test Results and Evaluation, continued

Senior Adult Data, 60-70 Years, SecureSack, continued

Test #	Age	Gender	First Opening	First Closing	Second Opening	Second Closing	Pass/ Fail	Comment	Test Site	Tester
76	66	F	0:20	0:03	n/a	n/a	Pass	Easy	15	2
77	61	F	0:36	0:04	n/a	n/a	Pass	Easy	16	6
78	68	F	1:21	0:05	0:16	0:05	Pass	Medium	16	6
79	63	F	0:45	0:07	n/a	n/a	Pass	Easy	16	1
80	68	F	2:10	0:04	0:03	0:04	Pass	Medium	16	1
81	62	F	0:37	0:06	n/a	n/a	Pass	Easy	16	1
82	66	F	0:44	0:04	n/a	n/a	Pass	Easy	17	2
83	63	F	1:02	0:05	0:03	0:05	Pass	Easy	17	2
84	68	F	0:39	0:07	n/a	n/a	Pass	Easy	2	2
85	60	F	1:18	0:06	0:05	0:04	Pass	Easy	19	6
86	70	F	2:06	0:04	0:17	0:07	Pass	Medium	19	6
87	67	F	0:31	0:05	n/a	n/a	Pass	Easy	2	1
88	62	F	0:50	0:03	n/a	n/a	Pass	Easy	1	3
89	70	F	1:19	0:05	0:12	0:08	Pass	Medium	18	6
90	67	F	2:40	n/a	n/a	n/a	Fail	Hard	18	6
91	65	F	0:48	0:07	n/a	n/a	Pass	Easy	18	1
92	66	F	0:35	0:05	n/a	n/a	Pass	Easy	18	1
93	68	F	1:03	0:06	0:09	0:06	Pass	Easy	18	1
94	64	F	0:50	0:08	n/a	n/a	Pass	Medium	18	1
95	61	F	0:18	0:04	n/a	n/a	Pass	Easy	2	3
96	70	F	1:35	0:07	0:18	0:05	Pass	Medium	2	3
97	65	F	0:34	0:06	n/a	n/a	Pass	Easy	17	3
98	67	F	2:15	0:05	0:06	0:07	Pass	Hard	17	3
99	60	F	0:27	0:04	n/a	n/a	Pass	Easy	17	3
100	63	F	0:49	0:06	n/a	n/a	Pass	Easy	17	3

Test Results and Evaluation, continued

Senior Adult Data, 50-70 Years, SecureSack, continued

TREAD GLOBAL, INC.
TESTING RESULTS SUMMARY
MAY 25, 2018

Adult Testing Results

Following is a summary of the adult testing results per CFR Title 16, Part 1700:

Total packages opened	130
Total packages resecured	130
Total packages opened by males	39
Total packages resecured by males	39
Total packages opened by females	91
Total packages resecured by females	91

Mean opening times for total openings	41.1s
Standard deviation for total opening times	30.4s
Mean opening times for total openings by males	39.9s
Standard deviation for total opening times by males	27.2s
Mean opening times for total openings by females	41.6s
Standard deviation for total opening times by females	31.7s

Mean resecuring times for total resecurings	5.3s
Standard deviation for total resecuring times	1.4s
Mean resecuring times for total resecurings by males	5.2s
Standard deviation for total resecuring times by males	1.2s
Mean resecuring times for total resecurings by females	5.3s
Standard deviation for total resecuring times by females	1.4s

Adult Testing Results, continued

The Percentage of Packages Tested Per Site (not to exceed 24%)

Site 1	6%
Site 2	9
Site 12	3
Site 13	4
Site 14	8
Site 15	14
Site 16	15
Site 17	18
Site 18	17
Site 19	6
	100%

The Percentage of Packages Tested Per Tester (not to exceed 35%)

Tester 1, SL	24%
Tester 2, CX	25
Tester 3, DC	16
Tester 4, JS	4
Tester 5, HZ	3
Tester 6, SZ	28
	100%

TREAD GLOBAL, INC.
TESTING RESULTS SUMMARY
MAY 25, 2018

Children's Testing Results

Following is a summary of the children's testing results per CFR Title 16, Part 1700:

	First Opening	Second Opening
Total packages opened	**0**	**0**
Total packages opened by males, 42-44 months	0	0
Total packages opened by males, 45-48 months	0	0
Total packages opened by males, 49-51 months	0	0
Total packages opened by females, 42-44 months	0	0
Total packages opened by females, 45-48 months	0	0
Total packages opened by females, 49-51 months	0	0
Mean opening times for total openings	n/a	
Standard deviation for total opening times	n/a	

Children's Testing Results, continued

The Percentage of Packages Tested Per Site (not to exceed 24%)

Site 1	6%
Site 2	4
Site 3	4
Site 4	6
Site 5	14
Site 6	4
Site 7	10
Site 8	10
Site 9	6
Site 10	8
Site 11	2
Site 12	14
Site 20	8
Site 21	4
	100%

The Percentage of Packages Tested Per Tester (not to exceed 35%)

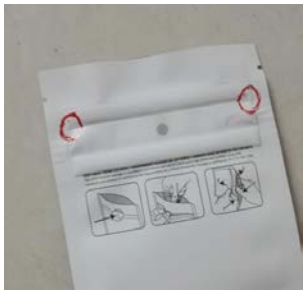
Tester 1, SL	16%
Tester 2, CX	20
Tester 3, DC	16
Tester 4, JS	16
Tester 5, HZ	18
Tester 6, SZ	14
	100%

Children

The children in this study attempted to open the package by using their fingers, fingernails and teeth to pull on the flaps. Several children tore the bag in their attempt to open it, but none were successful in opening the zipper and gaining access to the interior of the package. It appears that the skills needed to open the package exceed the cognitive abilities, strength, and motor development of most children in this age group.

Senior Adults

The senior adult participants in this study found a fair amount of difficulty in opening this package. Approximately 25% of the participants tore the bag as they attempted to open it, but the zipper assembly remained functional, maintaining child-resistant effectiveness. Two participants tore the bag in such a manner that it could not be reclosed; these were considered failures. (See photos below showing the weak points marked in red and two examples of torn bags.) In rating the difficulty of opening the package, 23% of the participants reported that it was medium to hard to open.



Conclusion

The results of this study indicate the SecureSack meets the requirements for child-resistant effectiveness and senior adult use effectiveness as required by the CPSC, CFR Title 16, Part 1700 for Poison Preventive Packaging.

Scope of Work

The scope of work for this analysis was subject to CFR Title 16, Part 1700. Durability testing was performed by appropriately opening and closing a package 20 times. Administrators found that this resulted in no noticeable adverse affect to the zipper assembly or the bag, thereby continuing to provide a secure closure.

This study did not further analyze material differences, long or short term deterioration to any part or aspect of the container, actual or hypothetical.

Intended Use of Report

The intended use of this report is for the client, Color Ad Packaging, Ltd., to evaluate their product, the SecureSack, subject to the Code of Federal Regulations Title 16, Part 1700, for child-resistant effectiveness and senior adult use effectiveness.

Intended User

The intended user of this report is Color Ad Packaging, Ltd. for the purpose of certification of their product, the SecureSack, for compliance as Poison Prevention Packaging as prescribed by CFR Title 16, Part 1700. Consent must be obtained from Tread Global, Inc. before this report may be disclosed or distributed to any other party including, but not limited to, the public through advertising, public relations, news, sales, or other media.

The Consumer Product Safety Commission places the responsibility for performance of specialized packaging, such as child-resistant packaging, on the manufacturer and packager. It is therefore the obligation of Color Ad Packaging, Ltd. to oversee the production and implementation of this product to insure its proper performance.

Continued

Tread Global, Inc., its Test Administrators, advisors, industry professionals, supervisors or any others representatives employed or consulted will not be responsible for matters of a legal nature that affect the product, except for information that he or she became aware of during the research involved in performing this test summary. Tread Global, Inc. and its representatives will not give testimony or appear in court because he or she conducted a test on the product in question, unless specific arrangements to do so have been made beforehand, or as otherwise required by law.

The industry professionals do not, nor will not approve, certify or endorse any specific child-resistant package. It is assumed that adults have access to and use of various tools to open packages. It is also assumed that all such tools are kept out of the reach of children.

Tread Global, Inc. has not knowingly withheld any significant information from this report and all statements and information in this report are true and correct.

Color Ad Packaging, Ltd. is advised to discuss matters of protocol concerns, testing, various requisite regulations, and certification with legal counsel.

Design, materials, manufacturing variances (such as color, size, printing, labeling, etc.), and other external influences could have an adverse effect on the performance of this child-resistant package if different than the packages provided to Tread Global, Inc. for testing. Child-resistant packages may not perform as tested when exposed to different conditions of application, storage, handling, or other variables. All package samples for testing and package material specifications have been provided by Color Ad Packaging, Ltd..

TREAD GLOBAL
International Product Sourcing and Development

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GENERAL CERTIFICATE OF CONFORMITY

The SecureSack

Color Ad Packaging, Ltd. certifies that the test unit, the SecureSack (3.62" x 5.86" x 1.5"), was evaluated and tested by a third party laboratory using the Consumer Product Safety Commission's protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700.

Tread Global, Inc. found the results of the study indicate that the test unit, the SecureSack (3.62" x 5.86" x 1.5"), fulfills the requirements for child-resistant effectiveness and senior adult use effectiveness as required by the Code of Federal Regulations (CFR) Title 16, Part 1700.

Effective Date: May 16, 2018

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Manufacturer: Color Ad Packaging, Ltd.
Canada, March 2018

Validation By: Tread Global, Inc.
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Participating Member ASTM, #1757717
Member of Child-Resistant Packaging Sub-Committee

COMPLIANCE STATEMENT

It is hereby certified that all materials used in the manufacture of parts in the quantity called for on the subject purchase order conforms to the materials and/or manufacturing specifications indicated in drawings or specifications as called for on said purchase order.

The SecureSack (3.62" x 5.86" x 1.5"), manufactured by Color Ad Packaging, Ltd., is in compliance with the Poison Prevention Act of the United States of America. (See Test Report "SecureSack".)

Standards and Protocol

As published from the United States Government Printing Office:

Code of Federal Regulations

Title 16 - Commercial Practices

Volume: 2
Date: 2012-01-01
Original Date: 2012-01-01
Title: PART 1700 - POISON PREVENTION PACKAGING
Context: Title 16 - Commercial Practices. CHAPTER II - CONSUMER PRODUCT SAFETY COMMISSION. SUBCHAPTER E - POISON PREVENTION PACKAGING ACT OF 1970 REGULATIONS.

Pt. 1700

PART 1700—POISON PREVENTION PACKAGING

Sec.
1700.1 Definitions.
1700.2 Authority.
1700.3 Establishment of standards for special packaging.
1700.4 Effective date of standards.
1700.5 Noncomplying package requirements.
1700.14 Substances requiring special packaging.
1700.15 Poison prevention packaging standards.
1700.20 Testing procedure for special packaging.
Authority: 15 U.S.C. 1471-76. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).
Source: 38 FR 21247, Aug. 7, 1973, unless otherwise noted.

§ 1700.1 Definitions.

(a) As used in this part:

(1) Act means the Poison Prevention Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74; 15 U.S.C. 1471-75), enacted December 30, 1970.

(2) Commission means the Consumer Product Safety Commission established by section 4 of the Consumer Product Safety Act (86 Stat. 1210; 15 U.S.C. 2053).

Standards and Protocol, continued

(3) Dietary supplement means any vitamin and/or mineral preparation offered in tablet, capsule, wafer, or other similar uniform unit form; in powder, granule, flake, or liquid form; or in the physical form of a conventional food but which is not a conventional food; and which purports or is represented to be for special dietary use by humans to supplement their diets by increasing the total dietary intake of one or more of the essential vitamins and/or minerals.

(b) Except for the definition of “Secretary,” which is obsolete, the definitions given in section 2 of the act are applicable to this part and are repeated herein for convenience as follows:

(1) [Reserved]

(2) Household substance means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is:

(i) A hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));

(ii) A food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(iii) A substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

(3) Package means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household and, for purposes of section 4(a)(2) of the act, also means any outer container or wrapping used in the retail display of any such substance to consumers. “Package” does not include:

(i) Any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; or

(ii) Any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) Special packaging means packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) Labeling means all labels and other written, printed, or graphic matter upon any household substance or its package, or accompanying such substance.

(Pub. L. 92-573, sec. 30(a), 86 Stat. 1231; (15 U.S.C. 2079(a)))
[38 FR 21247, Aug. 7, 1973, as amended at 41 FR 22266, June 2, 1976; 48 FR 57480, Dec. 30, 1983]

Standards and Protocol, continued

§ 1700.2 Authority.

Authority under the Poison Prevention Packaging Act of 1970 is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

§ 1700.3 Establishment of standards for special packaging.

(a) Pursuant to section 3 of the act, the Commission, after consultation with the technical advisory committee provided for by section 6 of the act, may establish by regulation standards for the special packaging of any household substance if the Commission finds:

(1) That the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) That the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing such a standard, the Commission shall consider:

(1) The reasonableness of such standard;

(2) Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) The manufacturing practices of industries affected by the act; and

(4) The nature and use of the household substance.

(c) In the process of establishing such a standard, the Commission shall publish its findings and reasons therefor and shall cite the sections of the act that authorize its action.

(d) In establishing such standards, the Commission shall not prescribe specific packaging designs, product content, package quantity, or labeling except for labeling under section 4(a)(2) of the act. Regarding a household substance for which special packaging is required by regulation, the Commission can prohibit the packaging of such substance in a package which the Commission determines is unnecessarily attractive to children.

(e) Promulgations pursuant to section 3 of the act shall be in accordance with section 5 of the act as to procedure.

Standards and Protocol, continued

§ 1700.4 Effective date of standards.

(a) The FR document promulgating a regulation establishing a child protection packaging standard shall indicate the standard's effective date. Section 9 of the act specifies that the effective date shall not be sooner than 180 days or later than 1 year from the date the standard is promulgated in the Federal Register unless the Commission, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register the reason for such finding, in which case such earlier effective date shall apply.

(b) Upon becoming effective, a child protection packaging standard shall apply only to household substances packaged on and after its effective date.

§ 1700.5 Noncomplying package requirements.

To make household substances that are subject to requirements for special packaging readily available to elderly or handicapped persons who are unable to use those substances in special packaging, section 4(a) of the act authorizes manufacturers and packers to package such substances in noncomplying packaging of a single size provided that complying packaging is also supplied and the noncomplying packages are conspicuously labeled to indicate that they should not be used in households where young children are present. The purpose of this § 1700.5 is to implement section 4(a) of the act by prescribing requirements for the labeling of noncomplying packages.

(a) Labeling statement. (1) The statement “This Package for Households Without Young Children” shall appear conspicuously, and in accordance with all of the requirements of paragraph (a) of this section, on the package of any household substance subject to the special packaging requirements of this part 1700 that is supplied in noncomplying packaging under section 4(a) of the act, unless the package bears the substitute labeling statement in accordance with all of the requirements of paragraph (b) of this section.

(2) The statement required by paragraph (a)(1) of this section shall appear on the principal display panel of the immediate container as well as on the principal display panel of any outer container or wrapping used in the retail display of the substance. If a package bears more than one principal display panel, the required statement shall appear on each principal display panel of the immediate container as well as on each principal display panel of any outer container or wrapping used in the retail display of the substance. The principal display panel is the part of the labeling most likely to be displayed, presented, shown, or examined.

(3) The required labeling statement shall appear within the borderline of a square or rectangle on the principal display panel in conspicuous and easily legible capital letters, shall be in distinct contrast, by typography, layout, color, or embossing, to other matter on the package, and shall appear in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(4) The declaration shall be in letters in type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type-size specifications:

Standards and Protocol, continued

(i) Not less than 1/16 inch in height on packages the principal display panel of which has an area of 7 square inches or less.

(ii) Not less than 3/32 inch in height on packages the principal display panel of which has an area of more than 7 but not more than 15 square inches.

(iii) Not less than 1/8 inch in height on packages the principal display panel of which has an area of more than 15 but not more than 25 square inches.

(iv) Not less than 3/16 inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(v) Not less than 1/4 inch in height on packages the principal display panel of which has an area of more than 100 square inches.

(5)(i) For the purpose of obtaining uniform type size for the required statement for all packages of substantially the same size, the area of the principal display panel is the area of the side or surface that bears the principal display panel, which shall be:

(A) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel, the product of the height times the width of that side.

(B) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference.

(C) In the case of any other shape of container, 40 percent of the total surface of the container; however, if such container presents an obvious principal display (such as the top of a triangular or circular package), the area shall consist of the entire area of such obvious principal display panel.

(ii) In determining the area of the principal display panel exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, the labeling statement required by this section to appear on the principal display panel shall appear within that 40 percent of the circumference most likely to be displayed, presented, shown, or examined.
(b) Substitute labeling statement. If the area of the principal display panel, as determined in accordance with paragraph (a)(5) of this section, is too small to accommodate the statement required by paragraph (a)(1) using the type size required by paragraph (a)(4), the substitute statement “Package Not Child-Resistant” may be used. This substitute statement must comply with all of the requirements for size, placement, and conspicuousness prescribed by paragraph (a) of this section.

[40 FR 4650, Jan. 31, 1975]

Standards and Protocol, continued

§ 1700.14 Substances requiring special packaging.

(a) Substances. The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

(1) Aspirin. Any aspirin-containing preparation for human use in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following:

(i) Effervescent tablets containing aspirin, other than those intended for pediatric use, provided the dry tablet contains not more than 15 percent aspirin and has an oral LD-50 in rats of 5 grams or more per kilogram of body weight.

(ii) Unflavored aspirin-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 15.4 grains of aspirin per unit dose and that contain no other substance subject to the provisions of this section.

(2) Furniture polish. Nonemulsion type liquid furniture polishes containing 10 percent or more of mineral seal oil and/or other petroleum distillates and having a viscosity of less than 100 Saybolt universal seconds at 100 °F., other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (d).

(3) Methyl salicylate. Liquid preparations containing more than 5 percent by weight of methyl salicylate, other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(4) Controlled drugs. Any preparation for human use that consists in whole or in part of any substance subject to control under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) and that is in a dosage form intended for oral administration shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(5) Sodium and/or potassium hydroxide. Household substances in dry forms such as granules, powder, and flakes, containing 10 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, and all other household substances containing 2 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(6) Turpentine. Household substances in liquid form containing 10 percent or more by weight of turpentine shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

Standards and Protocol, continued

(7) Kindling and/or illuminating preparations. Prepackaged liquid kindling and/or illuminating preparations, such as cigarette lighter fuel, charcoal lighter fuel, camping equipment fuel, torch fuel, and fuel for decorative or functional lanterns, which contain 10 percent or more by weight of petroleum distillates and have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(8) Methyl alcohol (methanol). Household substances in liquid form containing 4 percent or more by weight of methyl alcohol (methanol), other than those packaged in pressurized spray containers, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(9) Sulfuric acid. Household substances containing 10 percent or more by weight of sulfuric acid, except such substances in wet-cell storage batteries, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(10) Prescription drugs. Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Sublingual dosage forms of nitroglycerin.

(ii) Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams or less.

(iii) Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 grams of the equivalent of erythromycin.

(iv) Cyclically administered oral contraceptives in manufacturers' mnemonic (memory-aid) dispenser packages that rely solely upon the activity of one or more progestogen or estrogen substances.

(v) Anhydrous cholestyramine in powder form.

(vi) All unit dose forms of potassium supplements, including individually-wrapped effervescent tablets, unit dose vials of liquid potassium, and powdered potassium in unit-dose packets, containing not more than 50 milliequivalents of potassium per unit dose.

(vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package or not more than a concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to this § 1700.14(a)(10).

(viii) Betamethasone tablets packaged in manufacturers' dispenser packages, containing no more than 12.6 milligrams betamethasone.

(ix) Pancrelipase preparations in tablet, capsule, or powder form and containing no other substances subject to this § 1700.14(a)(10).

Standards and Protocol, continued

(x) Prednisone in tablet form, when dispensed in packages containing no more than 105 mg. of the drug, and containing no other substances subject to this § 1700.14(a)(10).

(xi)-(xii) [Reserved]

(xiii) Mebendazole in tablet form in packages containing not more than 600 mg. of the drug, and containing no other substance subject to the provisions of this section.

(xiv) Methylprednisolone in tablet form in packages containing not more than 84 mg of the drug and containing no other substance subject to the provisions of this section.

(xv) Colestipol in powder form in packages containing not more than 5 grams of the drug and containing no other substance subject to the provisions of this section.

(xvi) Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin.

(xvii) Conjugated Estrogens Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 32.0 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).

(xviii) Norethindrone Acetate Tablets, U.S.P., when dispensed in mnemonic packages containing not more than 50 mg of the drug and containing no other substances subject to this § 1700.14(a)(10).

(xix) Medroxyprogesterone acetate tablets.

(xx) Sacrosidase (sucrase) preparations in a solution of glycerol and water.

(xxi) Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.

(xxii) Colesevelam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug.

(xxiii) Sevelamer carbonate in powder form in packages containing not more than 2.4 grams of the drug.

(11) Ethylene glycol. Household substances in liquid form containing 10 percent or more by weight of ethylene glycol packaged on or after June 1, 1974, except those articles exempted by 16 CFR 1500.83, shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

Standards and Protocol, continued

(12) Iron-containing drugs. With the exception of: (i) Animal feeds used as vehicles for the administration of drugs, and (ii) those preparations in which iron is present solely as a colorant, noninjectable animal and human drugs providing iron for therapeutic or prophylactic purposes, and containing a total amount of elemental iron, from any source, in a single package, equivalent to 250 mg or more elemental iron in a concentration of 0.025 percent or more on a weight to volume basis for liquids and 0.025 percent or more on a weight to volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(13) Dietary supplements containing iron. Dietary supplements, as defined in § 1700.1(a)(3), that contain an equivalent of 250 mg or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Preparations in which iron is present solely as a colorant; and

(ii) Powdered preparations with no more than the equivalent of 0.12 percent weight-to-weight elemental iron.

(14) [Reserved]

(15) Solvents for paint or other similar surface-coating material. Prepackaged liquid solvents (such as removers, thinners, brush cleaners, etc.) for paints or other similar surface-coating materials (such as varnishes and lacquers), that contain 10 percent or more by weight of benzene (also known as benzol), toluene (also known as toluol), xylene (also known as xylol), petroleum distillates (such as gasoline, kerosene, mineral seal oil, mineral spirits, naphtha, and Stoddard solvent, etc.), or combinations thereof, and that have a viscosity of less than 100 Saybolt universal seconds at 100 °F., shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(16) Acetaminophen. Preparations for human use in a dosage form intended for oral administration and containing in a single package a total of more than one gram acetaminophen shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except the following—

(i) Effervescent tablets or granules containing acetaminophen, provided the dry tablet or granules contain less than 15 percent acetaminophen, the tablet or granules have an oral LD-50 of 5 grams or greater per kilogram of body weight, and the tablet or granules contain no other substance subject to the provisions of this section.

(ii) Unflavored acetaminophen-containing preparations in powder form (other than those intended for pediatric use) that are packaged in unit doses providing not more than 13 grains of acetaminophen per unit dose and that contain no other substance subject to this § 1700.14(a).

Standards and Protocol, continued

(17) Diphenhydramine. Preparations for human use in a dosage form intended for oral administration and containing more than the equivalent of 66 mg diphenhydramine base in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), if packaged on or after February 11, 1985.

(18) Glue removers containing acetonitrile. Household glue removers in a liquid form containing more than 500 mg of acetonitrile in a single container.

(19) Permanent wave neutralizers containing sodium bromate or potassium bromate. Home permanent wave neutralizers, in a liquid form, containing in single container more than 600 mg of sodium bromate or more than 50 mg of potassium bromate.

(20) Ibuprofen. Ibuprofen preparations for human use in a dosage form intended for oral administration and containing one gram (1,000 mg) or more of ibuprofen in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(21) Loperamide. Preparations for human use in a dosage form intended for oral administration and containing more than 0.045 mg of loperamide in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(22) Mouthwash. Except as provided in the following sentence, mouthwash preparations for human use and containing 3 g or more of ethanol in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c). Mouthwash products with nonremovable pump dispensers that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single unit are exempt from this requirement. The term “mouthwash” includes liquid products that are variously called mouthwashes, mouthrinses, oral antiseptics, gargles, fluoride rinses, anti-plaque rinses, and breath fresheners. It does not include throat sprays or aerosol breath fresheners.

(23) Lidocaine. Products containing more than 5.0 mg of lidocaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(24) Dibucaine. Products containing more than 0.5 mg of dibucaine in a single package (i.e., retail unit) shall be packaged in accordance with the provisions of § 1700.15 (a) and (b).

(25) Naproxen. Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

(26) Ketoprofen. Ketoprofen preparations for human use and containing more than 50 mg of ketoprofen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b) and (c).

Standards and Protocol, continued

(27) Fluoride. Household substances containing more than the equivalent of 50 milligrams of elemental fluoride per package and more than the equivalent of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c).

(28) Minoxidil. Minoxidil preparations for human use and containing more than 14 mg of minoxidil in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c). Any applicator packaged with the minoxidil preparation and which it is reasonable to expect may be used to replace the original closure shall also comply with the provisions of § 1700.15(a), (b) and (c).

(29)Methacrylic acid. Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: (i) the methacrylic acid is contained by the absorbent material so that no free liquid is within the device, and (ii) under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

(30) Over-the-Counter Drug Products. (i) Any over-the-counter (OTC) drug product in a dosage form intended for oral administration that contains any active ingredient that was previously available for oral administration only by prescription, and thus was required by paragraph (a)(10) of this section to be in special packaging, shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c). This requirement applies whether or not the amount of that active ingredient in the OTC drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply if the OTC drug product contains only active ingredients of any oral drug product or products approved for OTC marketing based on an application for OTC marketing submitted to the Food and Drug Administration (FDA) by any entity before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this § 1700.14 otherwise applicable to an OTC drug product remains in effect.

(ii) For purposes of this paragraph (30), active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of humans; and drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance (active ingredient), generally, but not necessarily, in association with one or more other ingredients. (These terms are intended to have the meanings assigned to them in the regulations of the Food and Drug Administration appearing at 21 CFR 201.66 (2001) and 21 CFR 314.3 (2000), respectively.)

(31) Hazardous substances containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are hazardous substances as defined in the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261(f)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100 °F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

Standards and Protocol, continued

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols, or pump-or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Writing markers and ballpoint pens exempted from labeling requirements under the FHSA by 16 CFR 1500.83.

(iii) Products from which the liquid cannot flow freely, including but not limited to paint markers and battery terminal cleaners. For purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

(32) Drugs and cosmetics containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are drugs or cosmetics as defined in the Federal Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. 321(a)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100 °F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols, or pump-or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Products from which the liquid cannot flow freely, including but not limited to makeup removal pads. For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

(b) Sample packages. (1) The manufacturer or packer of any of the substances listed under paragraph (a) of this section as substances requiring special packaging shall provide the Commission with a sample of each type of special packaging, as well as the labeling for each size product that will be packaged in special packaging and the labeling for any noncomplying package. Sample packages and labeling should be sent to the Consumer Product Safety Commission, Office of Compliance, 4330 East West Highway, Washington, DC 20207.

(2) Sample packages should be submitted without contents when such contents are unnecessary for demonstrating the effectiveness of the packaging.

(3) Any sample packages containing drugs listed under paragraph (a) of this section shall be sent by registered mail.

(4) As used in paragraph (b)(1) of this section, the term manufacturer or packer does not include pharmacists and other individuals who dispense, at the retail or user level, drugs listed under paragraph (a) of this section as requiring special packaging.

Standards and Protocol, continued

(c) Applicability. Special packaging standards for drugs listed under paragraph (a) of this section shall be in addition to any packaging requirements of the Federal Food, Drug, and Cosmetic Act or regulations promulgated thereunder or of any official compendia recognized by that act.

(Pub. L. 91-601, secs. 2(4), 3, 5, 85 Stat. 1670-72; 15 U.S.C. 1471(4), 1472, 1474; Pub. L. 92-573, 86 Stat. 1231; 15 U.S.C. 2079(a)) [38 FR 21247, Aug. 7, 1973]

§ 1700.15 Poison prevention packaging standards.

To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commission has determined that packaging designed and constructed to meet the following standards shall be regarded as "special packaging" within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with § 1700.14.

(a) General requirements. The special packaging must continue to function with the effectiveness specifications set forth in paragraph (b) of this section when in actual contact with the substance contained therein. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging. The special packaging must also continue to function with the effectiveness specifications set forth in paragraph (b) of this section for the number of openings and closings customary for its size and contents. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other such relevant factors which establish that, for the duration of normal use, the effectiveness specifications of the packaging would not be expected to lessen.

(b) Effectiveness specifications. Special packaging, tested by the method described in § 1700.20, shall meet the following specifications:

(1) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(2) Ease of adult opening—(i) Senior-adult test. Except for products specified in paragraph (b)(2)(ii) of this section, special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test of § 1700.20(a)(3).

(ii) Younger-adult test—(A) When applicable. Products that must be in aerosol form and products that require metal containers, under the criteria specified below, shall have an effectiveness of not less than 90% for the younger-adult test of § 1700.20(a)(4). The senior-adult panel test of § 1700.20(a)(3) does not apply to these products. For the purposes of this paragraph, metal containers are those that have both a metal package and a recloseable metal closure, and aerosol products are self-contained pressurized products.

Standards and Protocol, continued

(B) Determination of need for metal or aerosol container—(1) Criteria. A product will be deemed to require metal containers or aerosol form only if:

(i) No other packaging type would comply with other state or Federal regulations,

(ii) No other packaging can reasonably be used for the product's intended application,

(iii) No other packaging or closure material would be compatible with the substance,

(iv) No other suitable packaging type would provide adequate shelf-life for the product's intended use, or

(v) Any other reason clearly demonstrates that such packaging is required.

(2) Presumption. In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product, or another product of identical composition, has previously been marketed in packaging using either a nonmetal package or a nonmetal closure.

(3) Justification. A manufacturer or packager of a product that is in a metal container or aerosol form that the manufacturer or packager contends is not required to comply with the SAUE requirements of § 1700.20(a)(3) shall provide, if requested by the Commission's staff, a written explanation of why the product must have a metal container or be an aerosol. Manufacturers and packagers who wish to do so voluntarily may submit to the Commission's Office of Compliance a rationale for why their product must be in metal containers or be an aerosol. In such cases, the staff will reply to the manufacturer or packager, if requested, stating the staff's views on the adequacy of the rationale.

(c) Reuse of special packaging. Special packaging for substances subject to the provisions of this paragraph shall not be reused.

(d) Restricted flow. Special packaging subject to the provisions of this paragraph shall be special packaging from which the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once.

(Secs. 2(4), 3, 5, 84 Stat. 1670-72; 15 U.S.C. 1471(4), 1472, 1474)

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37734, July 21, 1995]

§ 1700.20 Testing procedure for special packaging.

(a) Test protocols—(1) General requirements—(i) Requirements for packaging. As specified in § 1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this § 1700.20.

Standards and Protocol, continued

(ii) Condition of packages to be tested—(A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies:

(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.

(B) Reclosable packages—adult tests. In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to “take a set.” If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) Child test—(i) Test subjects—(A) Selection criteria. Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20% of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40% of the children in each group shall be of age 45-48 months, and 30% of the children in each group shall be of age 49-51 months. The children's ages in months shall be calculated as follows:

(1) Arrange the birth date and test date by the numerical designations for month, day, and year (e.g., test date: 8/3/1990; birth date: 6/23/1986).

(2) Subtract the month, day, and year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days. (e.g.,

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this value to the number of months that was obtained when the birth date was subtracted from the test date (i.e., 4 × 12 = 48; 48 + 2 = 50). This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

Standards and Protocol, continued

(4) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is −16 or less, subtract 1 month. If the number of days is between −15 and +15 inclusive, no change is made in the number of months. Thus, for the example given above, the number of days is −20, and the number of months is therefore 50 − 1 = 49 months.

(B) Gender distribution. The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. A parent or guardian of each child shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) Test failures. A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound (11.4 kg) child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) Sequential test. The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30% of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in table 1 are cumulative.

Standards and Protocol, continued

Table 1—Number of Openings: Acceptance (Pass), Continue Testing, and Rejection (Fail) Criteria for the First 5 Minutes and the Full 10 Minutes of the Children's Protocol Test

Test Panel	Cumulative number of children	Package Openings					
		First 5 Minutes			Full 10 Minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0-3	4-10	11+	0-5	6-14	15+
2	100	4-10	11-18	19+	6-15	16-24	25+
3	150	11-18	19-25	26+	16-25	26-34	35+
4	200	19-30	--	31+	26-40	--	41+

(iv) Test procedures. The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children, for example, their customary nursery school or regular kindergarten. No child shall test more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

Standardized Child Test Instructions

1. Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials (e.g., the closure liner) to “take a set.” Application torques must be recorded in the test report.

2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

3. Reclosable packages shall be opened and properly resecured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and resecuring shall not be done in the presence of the children. (In the adult-resecuring test, the tester must not open and resecure the package prior to the test.) If multiple openings/resecurings are to be used, each of four (4) testers shall open and properly resecure one fourth of the packages once and then shall open and properly resecure each package a second, third, fourth, through tenth (or other specified number) time, in the same sequence as the first opening and resecuring. The packages shall not be opened and resecured again prior to testing. The name of each tester and the package numbers that he/she opens and resecures shall be recorded and reported. It is not necessary for the testers to protocol test the packages that they opened and resecured.

Standards and Protocol, continued

4. The children shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.

5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.

6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.

7. The tester shall talk to the children to make them feel at ease.

8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.

9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.
10. The tester shall use a stopwatch(s) or other timing devices to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.

11. To begin the test, the tester shall hand the children identical packages and say, “PLEASE TRY TO OPEN THIS FOR ME.”

12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversation with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., “please try to open the package”).

14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).

15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the final results.

16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.

17. A child shall not be allowed to try to open the other child's package.

Standards and Protocol, continued

18. If a child opens his/her package, the tester shall say, “THANK YOU,” take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.

19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate “demo” package shall be used for the demonstration.

20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.

21. The tester shall say, “WATCH ME OPEN MY PACKAGE.”

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, “NOW YOU TRY TO OPEN YOUR PACKAGES.”

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, “YOU CAN USE YOUR TEETH IF YOU WANT TO.” This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, “THANK YOU FOR HELPING.” If children were told that they could use their teeth, the tester shall say, “I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN” In addition, the tester shall say, “NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK.”

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

Standards and Protocol, continued

(3) Senior-adult panel—(i) Test subjects. Use a group of 100 senior adults. Not more than 24% of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability.

(ii) Screening procedures. Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or "special") closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm±18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce±1/2 ounce for the CT-type closure and 8 drams±4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.

(iv) Test procedures. The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

Test Instructions for Senior Test

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability that would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Examples of the forms used by the Commission staff for testing are shown at § 1700.20(d). Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

Standards and Protocol, continued

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the package are the only exceptions.

6. To begin the first 5-minute test period, the tester says, “I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP.” (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, “PLEASE OPEN THIS PACKAGE ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, “PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.” After the participant opens the package, the tester says, “PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resecuring times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, “ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?” If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, “THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, “PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.” After the participant opens the package, the tester says, “PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.” (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

Standards and Protocol, continued

12. After the 1-minute test, or when the participant has opened and finished closing the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, “ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?” If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, “PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE.” The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, “PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE.” The time to open and resecure, or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-seniors panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

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 resecuring 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 resecuring 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.

(b) The standards published as regulations issued for the purpose of designating particular substances as being subject to the requirements for special packaging under the act will stipulate the percent of child-resistant effectiveness and adult-use effectiveness required for each and, where appropriate, will include any other conditions deemed necessary and provided for in the act.

Standards and Protocol, continued

(c) It is recommended that manufacturers of special packaging, or producers of substances subject to regulations issued pursuant to the act, submit to the Commission summaries of data resulting from tests conducted in accordance with this protocol.

(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 photographs(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.

Standards and Protocol, continued

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-resecuring test instructions. CPSC will use the adult-resecuring test where an objective determination (e.g., visual or mechanical) that a package is properly resecured cannot be made.

The adult-resecuring test is performed as follows:

Adult-Resecuring 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 resecured 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 resecured by adults shall be tested by children according to the child-test procedures to determine if the packages have been properly resecured. The packages are given to the children without being opened or resecured again for any purpose.

Standards and Protocol, continued

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

a. Adult use effectiveness.

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

Standards and Protocol, continued

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 resecured; packages opened by males and by females; and packages resecured 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 resecuring times and standard deviation for total resecurings, total resecurings by females and total resecurings 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.

Standards and Protocol, continued

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

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970. The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened and properly closed by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

1. I will give you a package and ask you to read the instructions and open and properly close the package.

2. I will then give you an identical package, and ask you to open and properly close it.

3. I may ask you to open some other types of packages.

4. The packages may be empty or they may contain a product.

5. I will ask you whether you think the child-resistant package was easy or hard to use.

Standards and Protocol, continued

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.

Birthdate
Signature
Date
Zip Code

Office Use

Site:
Sample Number:
Test Number:
Package Number:

2. Unit-dose packages.

[Testing Organization's Letterhead]

Unit Dose Child-Resistant Package Testing

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970.

The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Standards and Protocol, continued

Description of the Test

1. I will give you a package and ask you to read the instructions, open one unit, and remove the contents.

2. I will then give you an identical package, and ask you to open one unit and remove the contents.

3. I may ask you to open some other types of packages.

4. I will ask you whether you think the child-resistant package was easy or hard to use.

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.

Birthdate
Signature
Date
Zip Code

Office Use

Site:
Sample Number:
Test Number:
Package Number:

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37735, 37738, July 22, 1995]

TREAD GLOBAL
International Product Sourcing and Development

999 18th Street, Suite 3000, Denver, CO 80202
www.TreadGlobal.com Phone (303) 993-8943

GENERAL CERTIFICATE OF CONFORMITY
The Secure Sack

Dymapak certifies the test unit, the Secure Sack in two sizes 6" x 8" and 12" x 9", was tested and evaluated by two third party laboratories (listed below) using the Consumer Product Safety Commission's protocol and standards for Poison Prevention Packaging as required by the Code of Federal Regulations (CFR) Title 16, Part 1700, Part 1700.15 (1995), and Part 1700.20 (1995). Based on the bracketing test results, similar Secure Sacks from this manufacturer, from identical materials, and in additional sizes, could have similar testing results.

Tread Global, Inc. found the results of the study indicate that the test unit, the 12" x 9" Secure Sack, fulfills the requirements for child-resistant effectiveness and senior adult use effectiveness as required by the Code of Federal Regulations (CFR) Title 16, Part 1700, Part 1700.15 (1995), and Part 1700.20 (1995), for Poison Prevention Packaging.

Bitner Associates, Inc. reports the test unit, the 6" x 8" Secure Sack, meets the standards for poison prevention packaging per current CFR Title 16, Part 1700.20.

Effective Date: March 31, 2018

DYMAPAK

Company: Dymapak
725 River Road, Suite 213
Edgewater, NJ 07020
(917) 210-1067
dymapak.com

Manufacturer: Quark Distribution, Inc.
12" x 9": China, February 2018
6" x 8": China, March 2017

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Participating Member ASTM, #1757717
Member of Child-Resistant Packaging Sub-Committee

Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL 60554
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COMPLIANCE STATEMENT

It is hereby certified that all materials used in the manufacture of parts in the quantity called for on the subject purchase order conforms to the materials and/or manufacturing specifications indicated in drawings or specifications as called for on said purchase order.

The Secure Sack in two sizes, 6" x 8" and 12" x 9", manufactured by Quark Distribution, Inc. for Dymapak, is in compliance with the Poison Prevention Act of the United States of America.