

July 12, 2016

To Whom It May Concern:

This documentation certifies that the pairings listed below have been tested by an independent third party and meet the requirements dictated by 16 CFR 1700:

M032 + G073, G073A, G073BK, G073F, G073P, G136B

Sincerely,

Container & Packaging Supply
Supply Chain Management Division

A note about certifications

A 16 CFR 1700 certification is awarded to the *combination* of a container and a closure, aka a package. In order to be compliant, and to have the proper certifications, the container *and* closure *combination* must be tested *together* by a third party.

This certification only permits the combinations listed above. This certification is nullified if you combine any of these listed items with any other item.



POISON PREVENTION PACKAGING
Test Report for
BOSTON ROUND DROPPER BOTTLE

July 6, 2016

CONDUCTED FOR
Glopak USA Corp.



TREAD
International Product



GLOBAL
Sourcing and Development

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

July 6, 2016

Kenneth Krell
Glopak USA Corp.
35 Engel Street
Hicksville, NY 11801

Dear Mr. Krell:

Attached is our report of the Poison Prevention Packaging testing that has been completed for your product, the 60 ml Boston Round Dropper Bottle.

Your product has been evaluated using the Consumer Product Safety Commission's (CPSC) protocols and standards. The test results show clearly that the Boston Round Dropper Bottle fulfills the requirements for Poison Prevention Packaging as required by the current Code of Federal Regulations (C.F.R.) Title 16, Part 1700 for senior adult use with resealing effectiveness.

Senior adult use with resealing effectiveness was 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
Member of Child-Resistant
Packaging Sub-Committee*



TREAD GLOBAL, INC.
POISON PREVENTION PACKAGING TEST REPORT FOR
BOSTON ROUND DROPPER BOTTLE
July 6, 2016

TABLE OF CONTENTS

	<u>Page</u>
Report Synopsis	1
Introduction	2
Test Parameters	3
Results and Discussion	5
Data Evaluation	
Senior Adult's Results, Boston Round Dropper Bottle	
Table 1, Summary	6
Individual Data	7
Children's Results, Boston Round Dropper Bottle	
Table 2, Summary	12
Individual Data	13
Conclusion	18
Limiting Conditions	19
Certificate of Compliance	21
Addendum	
Code of Federal Regulations Title 16, Part 1700	22



REPORT SYNOPSIS

July 6, 2016

Report issued to: Kenneth Krell
Glopak USA Corp.
35 Engel Street
Hicksville, NY 11801

Product tested: Boston Round Dropper Bottle

Manufacturer: Glopak USA Corp.

Testing dates: Testing began June 22, 2016
Testing ended July 6, 2016

Objective

Glopak USA Corp. submitted the Boston Round Dropper Bottle for analysis to determine if the container is in compliance with the Consumer Product Safety Commission's (CPSC) protocol and standards for Poison Prevention Packaging as required by the current Code of Federal Regulations (CFR) Title 16, Part 1700 (see Addendum) for senior adult use with resealing effectiveness.

Procedures

The protocols for the evaluation of packaging for poison prevention (current CFR Title 16, Part 1700) were strictly adhered to for this study, unless otherwise documented, using the amended senior adult test which includes children attempting to open containers previously closed by a senior adult, providing a senior adult use with resealing effectiveness result. The standard child-resistant effectiveness test is rarely applied to senior adult use with resealing effectiveness tests, and was not done for the Boston Round Dropper Bottle.

Participants

In the course of this study, 100 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 Boston Round Dropper Bottle meets and exceeds the standards for Poison Prevention Packaging as required by CFR Title 16, Part 1700 for senior adult use with resealing effectiveness.

TREAD GLOBAL, INC.

INTRODUCTION

July 6, 2016

Tread Global, Inc. is recognized in the field of consumer product testing and development, and has been employed by Glopak USA Corp. to ascertain if their product, the Boston Round Dropper Bottle, fulfills the Consumer Product Safety Commission's (CPSC) standards for Poison Prevention Packaging as set forth in current CFR Title 16, Part 1700. Tread Global, Inc. conducted poison prevention packaging testing for the Boston Round Dropper Bottle according to CPSC protocols for senior adult use with resealing effectiveness.

Tread Global, Inc. is an independent product development company who provides various testing services for a wide range of consumer products, specializing in child related safety testing. The testing company, who participated in the administration of this test, has extensive experience performing testing for consumer product safety.

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.

“Senior adult use with resealing effectiveness” indicates packaging that has been opened and resealed by a senior adult and subsequently given to a child to determine if the package has been properly resealed, evidenced by the child being unable to open the package.

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 100 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.

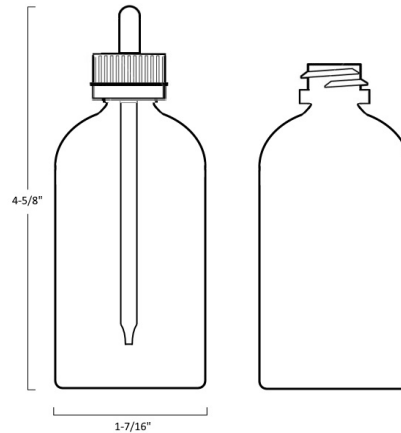
July 6, 2016

The Package

The product submitted for testing was the Boston Round Dropper Bottle, consisting of a 60 ml glass bottle and a push and turn cap. The cap has a central hole which accommodates the rubber bulb, which serves as a seal for the bottle and the attachment for the glass pipette. This configuration is referred to in this report as the “Boston Round Dropper Bottle”.

The bottle is type 3 clear glass. The 20-400 push and turn cap and its liner are constructed of black or white polypropylene (PP), a thermoplastic polymer. The bulb is constructed of black rubber. The pipette is 89 mm, type 1, constructed of clear glass.

For purposes of this test, each senior adult participant was given a bottle that had been opened once and resecured to 10 inch pounds of torque, 72 hours prior to testing. All of the units tested were empty. The Test Administrators asked the participants to open and close the package properly.



Continued

Participants

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).

In the children's testing phase of this study, 100 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). Each child was given a container that had been opened and resecured by a senior adult.

Test Administrators

Test Administrators were instructed to conduct the evaluation of the packaging in strict accordance with the standards and protocols required by the current CFR Title 16, Part 1700 and Title 40, Part 157.32.

Materials

The Boston Round Dropper Bottle is manufactured by Glopak USA Corp. The bottle and pipette are type 3 clear glass. The push and turn cap and its liner are constructed of black or white polypropylene (PP), a thermoplastic polymer used for its high resistance to chemical solvents, bases and acids, and its good fatigue resistance. The bulb is constructed of black rubber, an elastomer which is highly elastic and used for its qualities of being non-reactive, stable, waterproof and resistant to extreme environments and temperatures.

TREAD GLOBAL, INC.
RESULTS AND DISCUSSION
July 6, 2016

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:

- * Senior adult use with resealing effectiveness
- * Current Code Requirements

Senior Adult Use With Resealing Effectiveness

Results of the senior adult's testing appear in Table 1 of this report. This Table demonstrates that two senior adult participants were unsuccessful in opening the Boston Round Dropper Bottle within the allotted time frame.

Each child in the testing was given a bottle that had been opened and resealed by a senior adult, to determine how effectively the senior adults were tightening the Boston Round Dropper Bottle cap. The results of the children's portion of the testing appear in Table 2. This Table demonstrates that none of the children were able to open the senior adult sealed bottles.

Although the standard child-resistant effectiveness test is rarely applied to push and turn caps, such as the cap on the Boston Round Dropper Bottle, and therefore was not performed in this instance, the standard protocols for child-resistant effectiveness testing were followed.

The senior adult use with resealing effectiveness was calculated at 98%, exceeding the current CFR Title 16, Part 1700 minimum requirements for both senior adult use effectiveness and senior adult use with resealing effectiveness.

Per Title 16, Part 1700.20: The number of adult opening and resealing failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-resealed packages, equals the total number of failures. The total number of packages tested by adults minus the total number of failures equals the percent adult-use effectiveness.

Current Code Requirements

The testing of the senior adults and subsequent children's testing to determine the senior adult use with resealing effectiveness shows conclusively that the Boston Round Dropper Bottle meets and exceeds the Consumer Product Safety Commission's (CPSC) protocol and standards for Poison Prevention Packaging using the amended senior testing for resealing effectiveness as required by the current Code of Federal Regulations (CFR) Title 16, Part 1700.

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Table 1

**Summary of Package Opening Test Results for the Boston Round Dropper Bottle
 Evaluated by Senior Adults Age 50-70 Years
 For Senior Adult Use With Resecuring Effectiveness**

Age and Gender	Participants Tested	Successful Package Openings		Total Failures
		First Opening	Second Opening	
50-54 years old:				
Females	18	17	1	0
Males	7	6	1	0
Subtotal	25	23	2	0
55-59 years old:				
Females	17	14	3	0
Males	8	6	2	0
Subtotal	25	20	5	0
60-70 years old:				
Females	35	22	11	2
Males	15	11	4	0
Subtotal	50	33	15	2
Total	100	76	22	2

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.

Per CPSC protocol, those participants who opened and reclosed the package in under one minute were not retested.

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".

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Senior Adult Data, 50-54 Years, Boston Round Dropper Bottle

Test #	Age	Gender	First Opening & Closing	Second Opening & Closing	Pass/Fail	Comments	Test Site	Tester
1	53	M	0:35	n/a	Pass	Easy	8	3
2	54	M	0:42	n/a	Pass	Easy	1	1
3	50	M	0:38	n/a	Pass	Easy	6	5
4	54	M	1:04	0:15	Pass	Medium	2	1
5	53	M	0:41	n/a	Pass	Easy	10	6
6	52	M	0:31	n/a	Pass	Easy	8	3
7	51	M	0:35	n/a	Pass	Easy	6	5
8	50	F	0:32	n/a	Pass	Easy	8	3
9	53	F	0:49	n/a	Pass	Easy	8	3
10	53	F	0:48	n/a	Pass	Easy	1	1
11	51	F	0:43	n/a	Pass	Easy	1	1
12	53	F	0:33	n/a	Pass	Easy	1	1
13	52	F	0:39	n/a	Pass	Easy	6	5
14	53	F	1:42	0:32	Pass	Hard	6	5
15	52	F	0:38	n/a	Pass	Easy	2	1
16	51	F	0:42	n/a	Pass	Easy	2	1
17	54	F	1:13	0:20	Pass	Medium	10	6
18	54	F	0:52	n/a	Pass	Medium	10	6
19	51	F	0:39	n/a	Pass	Easy	10	6
20	53	F	0:53	n/a	Pass	Easy	3	2
21	50	F	0:51	n/a	Pass	Easy	8	3
22	54	F	1:29	0:47	Pass	Medium	8	3
23	51	F	0:44	n/a	Pass	Easy	7	4
24	53	F	0:37	n/a	Pass	Easy	6	5
25	52	F	0:43	n/a	Pass	Easy	6	5

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Senior Adult Data, 55-59 Years, Boston Round Dropper Bottle

Test #	Age	Gender	First Opening & Closing	Second Opening & Closing	Pass/Fail	Comments	Test Site	Tester
26	55	M	0:48	n/a	Pass	Easy	8	3
27	57	M	0:43	n/a	Pass	Easy	1	1
28	59	M	1:17	0:21	Pass	Hard	2	1
29	56	M	0:39	n/a	Pass	Easy	2	1
30	56	M	0:52	n/a	Pass	Easy	10	6
31	58	M	0:50	n/a	Pass	Medium	10	6
32	55	M	0:37	n/a	Pass	Easy	3	2
33	55	M	1:01	0:26	Pass	Medium	6	5
34	56	F	0:53	n/a	Pass	Medium	8	3
35	56	F	0:53	n/a	Pass	Easy	8	3
36	58	F	0:45	n/a	Pass	Easy	8	3
37	57	F	1:44	0:32	Pass	Hard	1	1
38	58	F	1:28	0:38	Pass	Hard	1	1
39	56	F	0:52	n/a	Pass	Easy	1	1
40	59	F	0:44	n/a	Pass	Easy	6	5
41	57	F	0:35	n/a	Pass	Easy	6	5
42	57	F	0:53	n/a	Pass	Easy	2	1
43	59	F	0:59	n/a	Pass	Easy	10	6
44	58	F	0:51	n/a	Pass	Easy	10	6
45	59	F	1:15	0:51	Pass	Medium	10	6
46	55	F	0:55	n/a	Pass	Easy	1	6
47	56	F	0:56	n/a	Pass	Medium	1	6
48	57	F	0:51	n/a	Pass	Medium	8	3
49	56	F	0:47	n/a	Pass	Easy	7	4
50	55	F	0:36	n/a	Pass	Easy	7	4

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Senior Adult Data, 60-70 Years, Boston Round Dropper Bottle

Test #	Age	Gender	First Opening & Closing	Second Opening & Closing	Pass/Fail	Comments	Test Site	Tester
51	661	M	0:46	n/a	Pass	Easy	8	3
52	62	M	0:55	n/a	Pass	Easy	1	1
53	63	M	1:09	0:21	Pass	Hard	1	1
54	62	M	0:57	n/a	Pass	Medium	6	5
55	63	M	0:47	n/a	Pass	Easy	6	5
56	64	M	1:33	0:35	Pass	Hard	10	6
57	61	M	0:36	n/a	Pass	Easy	10	6
58	65	M	1:12	0:44	Pass	Medium	10	6
59	63	M	0:43	n/a	Pass	Easy	3	2
60	65	M	0:50	n/a	Pass	Easy	11	2
61	62	M	0:54	n/a	Pass	Easy	8	3
62	60	M	0:44	n/a	Pass	Medium	8	3
63	67	M	1:38	0:52	Pass	Hard	7	4
64	63	M	0:48	n/a	Pass	Easy	6	6
65	61	M	0:35	n/a	Pass	Easy	6	5
66	62	F	0:57	n/a	Pass	Medium	8	3
67	65	F	1:24	0:50	Pass	Medium	8	3
68	69	F	1:42	0:54	Pass	Hard	8	3
69	67	F	0:53	n/a	Pass	Easy	1	1
70	69	F	> 5:00	1:33	Fail	Hard	1	1
71	61	F	0:53	n/a	Pass	Medium	1	1
72	64	F	0:56	n/a	Pass	Medium	1	1
73	65	F	1:31	0:56	Pass	Hard	6	5
74	64	F	0:42	n/a	Pass	Easy	6	5
75	66	F	1:03	0:40	Pass	Medium	2	1

TREAD GLOBAL, INC.

DATA EVALUATION

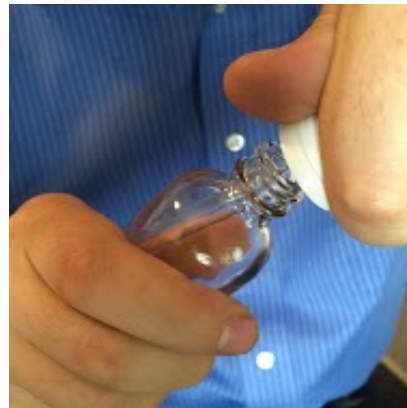
July 6, 2016

Test Results and Evaluation, continued**Senior Adult Data, 60-70 Years, Boston Round Dropper Bottle, continued**

Test #	Age	Gender	First Opening & Closing	Second Opening & Closing	Pass/Fail	Comments	Test Site	Tester
76	61	F	0:56	n/a	Pass	Medium	2	1
77	65	F	0:53	n/a	Pass	Easy	10	6
78	60	F	0:57	n/a	Pass	Medium	10	6
79	69	F	1:45	0:35	Pass	Hard	10	6
80	61	F	0:50	n/a	Pass	Easy	11	2
81	62	F	0:41	n/a	Pass	Easy	11	2
82	68	F	1:13	0:52	Pass	Medium	6	2
83	68	F	> 5:00	1:21	Fail	Hard	6	2
84	62	F	0:48	n/a	Pass	Easy	10	4
85	66	F	0:51	n/a	Pass	Medium	10	4
86	63	F	1:18	0:39	Pass	Medium	10	4
87	63	F	0:56	n/a	Pass	Easy	10	4
88	65	F	0:54	n/a	Pass	Easy	1	6
89	69	F	1:44	0:30	Pass	Medium	1	6
90	60	F	0:57	n/a	Pass	Medium	8	3
91	62	F	0:52	n/a	Pass	Easy	8	3
92	61	F	0:46	n/a	Pass	Easy	7	4
93	65	F	1:26	0:49	Pass	Hard	7	4
94	63	F	1:14	0:17	Pass	Medium	6	5
95	64	F	1:01	0:36	Pass	Medium	6	5
96	64	F	0:43	n/a	Pass	Easy	6	5
97	63	F	0:51	n/a	Pass	Medium	6	5
98	61	F	0:51	n/a	Pass	Medium	2	3
99	63	F	0:46	n/a	Pass	Easy	2	3
100	60	F	0:47	n/a	Pass	Medium	2	3

Test Results and Evaluation, continued

Senior Adult Data, 50-70 Years, the Boston Round Dropper Bottle, continued



TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Table 2

**Summary of Package Opening Test Results for the Boston Round Dropper Bottle
 Evaluated by Children 42 to 51 Months of Age
 For Senior Adult Use With Resecuring Effectiveness**

				Successful Package Openings				
				Before Demonstration		After Demonstration		
Age in Months	Males	Females	Total	Males	Females	Males	Females	Total
42-44	15	15	30	0	0	0	0	0
45-48	20	20	40	0	0	0	0	0
49-51	15	15	30	0	0	0	0	0
Total	50	50	100	0	0	0	0	0

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".

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Children's Data, 42-51 Months, the Boston Round Dropper Bottle

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

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Children's Data, 42-51 Months, the Boston Round Dropper Bottle, continued

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

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

Test Results and Evaluation, continued

Children's Data, 42-51 Months, the Boston Round Dropper Bottle, continued

Package #	Age in Months	Gender	Pass/ Failed Time	Test Site	Tester
51	46	F	Pass	8	3
52	46	F	Pass	8	3
53	47	F	Pass	9	2
54	48	F	Pass	9	2
55	46	F	Pass	5	4
56	45	F	Pass	6	5
57	46	F	Pass	2	1
58	48	F	Pass	2	1
59	47	F	Pass	10	6
60	45	F	Pass	10	6
61	48	F	Pass	3	2
62	48	F	Pass	3	2
63	46	F	Pass	6	3
64	46	F	Pass	10	4
65	45	F	Pass	10	4
66	45	F	Pass	1	6
67	47	F	Pass	1	6
68	48	F	Pass	8	3
69	46	F	Pass	6	5
70	47	F	Pass	6	5
71	49	M	Pass	8	3
72	50	M	Pass	9	2
73	51	M	Pass	5	4
74	49	M	Pass	5	4
75	50	M	Pass	6	5

TREAD GLOBAL, INC.
DATA EVALUATION
 July 6, 2016

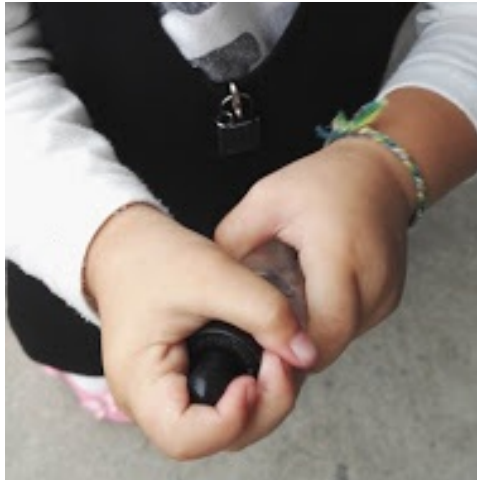
Test Results and Evaluation, continued

Children's Data, 42-51 Months, the Boston Round Dropper Bottle, continued

Package #	Age in Months	Gender	Pass/ Failed Time	Test Site	Tester
76	49	M	Pass	6	5
77	51	M	Pass	2	1
78	51	M	Pass	10	6
79	50	M	Pass	10	6
80	51	M	Pass	3	2
81	49	M	Pass	6	3
82	50	M	Pass	1	6
83	49	M	Pass	1	6
84	50	M	Pass	8	3
85	51	M	Pass	6	5
86	49	F	Pass	8	3
87	49	F	Pass	9	2
88	50	F	Pass	5	4
89	51	F	Pass	6	5
90	49	F	Pass	6	5
91	49	F	Pass	10	6
92	51	F	Pass	3	2
93	50	F	Pass	11	2
94	50	F	Pass	10	4
95	49	F	Pass	1	6
96	50	F	Pass	1	6
97	51	F	Pass	1	6
98	49	F	Pass	8	3
99	51	F	Pass	7	4
100	49	F	Pass	7	4

Test Results and Evaluation, continued

Children's Data, 42-51 Months, the Boston Round Dropper Bottle, continued



CONCLUSION

July 6, 2016

Senior Adults

Most of the senior adults in this study had little trouble with opening the Boston Round Dropper Bottle with only two senior adults failing. The senior adults easily closed the container within the allotted time.

Children

Most of the children attempted to open the Boston Round Dropper Bottle by turning the cap without pushing down or by pulling up on the cap. It appears that children in this age group do not have the skills needed to open the container, including the cognitive abilities, strength, and motor development required to push the cap down and simultaneously turn it.

Conclusion

Per Title 16, Part 1700.20: The number of adult opening and resealing failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-resealed packages, equals the total number of failures. The total number of packages tested by adults minus the total number of failures equals the percent adult use resealing effectiveness.

In the testing of the Boston Round Dropper Bottle, two senior adults failed to open the bottle, a 98% effectiveness rate.

In the children's testing of the Boston Round Dropper Bottle none of the children were able to open the bottle, a 0% failure rate. Therefore, the senior adult use with resealing effectiveness was calculated to be 98%, results that indicate the Boston Round Dropper Bottle meets and exceeds the requirements for senior adult use with resealing effectiveness as required by CPSC in the current CFR Title 16, Part 1700 for Poison Preventive Packaging.

TREAD GLOBAL, INC.
LIMITING CONDITIONS
July 6, 2016

Scope of Work

The scope of work for this analysis was subject to the C.F.R Title 16, Part 1700. Durability testing was performed by opening and closing a bottle 50 times. Administrators found that this resulted in no noticeable wear to the cap, continuous threads or the liner, 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

The intended use of this report is for the client, Glopak USA Corp., to evaluate their product, the Boston Round Dropper Bottle, subject to the Code of Federal Regulations Title 16, Part 1700.

Intended User

The intended user of this report is Glopak USA Corp. for the purpose of certification of their product, the Boston Round Dropper Bottle, for compliance as Poison Prevention Packaging as prescribed by the Consumer Product Safety Commission in 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 packager. It is therefore the obligation of Glopak USA Corp., as packager, to oversee the production and implementation of this product to insure its proper performance.

TREAD GLOBAL, INC.
LIMITING CONDITIONS
July 6, 2016

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.

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

Design, materials, manufacturing variances, 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 container samples for testing and package material specifications have been provided by Glopak USA Corp.



CERTIFICATE OF COMPLIANCE

Boston Round Dropper Bottle, 60 ml

Glopak USA Corp. certifies that the Boston Round Dropper Bottle 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 current Code of Federal Regulations (CFR) Title 16, Part 1700.

Tread Global, Inc. found the results of the study indicate that the test unit, the 60 ml Boston Round Dropper Bottle, fulfills the requirements for senior adult use with resealing effectiveness as required by the current Code of Federal Regulations (CFR) Title 16, Part 1700 for Poison Prevention Packaging.

Effective Date: July 6, 2016

Manufacturer: Glopak USA Corp.



Validation By: Tread Global, Inc.
999 18th Street, Suite 3000
Denver, CO 80202
(303) 993-8943
www.TreadGlobal.com



Test Supervisor: Jeremiah Buck
Director of Product Development
Tread Global, Inc.
Participating Member ASTM
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 60 ml Boston Round Dropper Bottle, manufactured by Glopak USA Corp., is in compliance with the Poison Prevention Act of the United States of America.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 6, 2016

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).

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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]

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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:

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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]

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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).

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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).

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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).

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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 xylo), 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).

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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).

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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:

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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 reseal 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., $4 \times 12 = 48$; $48 + 2 = 50$). 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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
 July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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 resealing 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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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 resealing process.

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

(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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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 resealing failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-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-resealing test.

A. Identification

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

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

3. Product manufacturer.

4. Closure model (trade name).

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

6. Closure manufacturer.

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

8. Closure liner material.

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

10. TAC seal material.

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

12. Package model.

13. Package material and color.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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 resealing times and standard deviation for total resealings, total resealings by females and total resealings by males.
4. The percentage of packages tested at each site as a percentage of total packages.
5. The percentage of packages tested by each tester as a percentage of total packages.
6. Methods of opening (e.g., normal opening, pried closure off, etc.)

Child Test

1. Openings in each 5-minute period, and total openings, for males and females in each age group.
2. Opening methods.
3. Mean opening times and standard deviation for each 5-minute test period.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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.

TREAD GLOBAL, INC.
ADDENDUM
CODE OF FEDERAL REGULATIONS TITLE 16, PART 1700
July 14, 2015

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]