

GENERAL CERTIFICATE OF CONFORMITY

1. Identification of the product covered by this certificate:

Mod Fuel™ Lines, by Mod Fuel™ E-liquid (Includes all lines manufactured by Mod Fuel™ E-Liquid: Chubby Bubble Vapes, Cultured E-Liquid, SodaLicious E-Liquid, Another Hard Candy E-Liquid, Paradise Vapes, Rox E-Liquid, Simply Fruit E-Liquid, Royal Tea E-Liquid, Pure Sherbet E-Liquid) 15ml, 30ml, 60ml and 120ml bottles.

2. Citation to each CPSC product safety regulation to which the product is being certified:

16 CFR Title 16 Part 1700.20

3. Identification of the U.S. Importer or Domestic manufacturing certifying compliance of the product:

Wolfgang Enterprise, Inc(FH Packaging)
829 S Lemon Ave, Suite A11D
Walnut, CA 91789
(See attached GCC from Wolfgang Enterprise, Inc)

4. Contact information for the individual maintaining records of test results:

Wolfgang Enterprise, Inc(FH Packaging)
829 S Lemon Ave, Suite A11D
Walnut, CA 91789
(See attached GCC from Wolfgang Enterprise, Inc)

5. Place where this product was manufactured:

Factory: Yiwu FH Plastics Co. Ltd. (FH Packaging)
No. 2277 Xue Feng West Road
Cheng Xi Street, Yiwu, Zhejiang Province, P. R. C. 322000 China

6. Date and place where this product was tested for compliance with the regulation(s) cited:

Testing conducted from June 30, 2015 – July 9, 2015
Bitner Associates, Inc. – Chicago and south, west villages thereof

7. Identification of any third-party facility on shoes testing the certificated depends:

Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, Illinois 60554

Evaluation of
CR Dropper Bottle
as a poison prevention package for

Factory: Yiwu FH Plastics Co.,Ltd.
2277 XUE FENG WEST ROAD, CHENG XI STREET,
YIWU, ZHEJIANG PROVINCE, P.R.C 32200

By

Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, Illinois 60554



Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL 60554
Ph. 708.738.5598

July 9, 2015

Wolfgang Enterprise, Inc (FH Packaging)
829 S Lemon Ave, Suite A11D
Walnut, CA 91789
Attention: Gang Wu;

Herein is our report titled **CR Dropper Bottle** as a Poison Protection Package for **Wolfgang Enterprise, Inc.**

The test unit was evaluated using the Consumer Product Safety Commission Protocol and Standards. The study indicates this **CR Dropper Bottle** fulfills the requirements for a Poison Prevention Package as per the current Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

After you have had an opportunity to read the report, I shall be pleased to review it with you.

Sincerely,
BITNER ASSOCIATES, Inc.

A handwritten signature in black ink that reads "John Bitner". The signature is written in a cursive, flowing style.

John Bitner
President



Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL 60554
Ph. 708.738.5598

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I. SUMMARY

Report to: **Wolfgang Enterprise, Inc (FH Packaging)**

829 S Lemon Ave, Suite A11D

Walnut, CA 91789

Date: July 9, 2015

Samples of: **CR Dropper Bottle**

Contract No.: 1371-195

Samples Received: June 28, 2015

Submitted by: Gang Wu

Objective

Wolfgang Enterprise, Inc submitted **CR Dropper Bottle** for a study to determine if bottle/closure is in compliance with the Consumer Product Safety Commission's (CPSC) current protocol and standards for poison prevention packaging Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Procedures

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

Panelists

In the course of this study 100 children (42 to 51 months of age) and 100 seniors (50 to 70 year-olds, 70% female) were employed.

Results

Results of the study indicate that the CR Dropper Bottle meets **standards for poison prevention packaging** according to current C.F.R. Title 16, Part 1700.20.

II. INTRODUCTION

Wolfgang Enterprise, Inc. wished to determine if **CR Dropper Bottle** fulfills the Consumer Product Safety Commission's (CPSC) current standards and protocol for poison prevention packaging set forth in the Code of Federal Regulations Title 16, Part 1700.20. Bitner Associates is a recognized testing laboratory facility for testing child-resistant packaging according to CPSC protocol was requested to evaluate the packaging using the above protocol.

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

In the course of this evaluation, the packaging was tested with panels consisting of 100 seniors (50 to 70 year-olds, 70% female) and 100 children (42 to 51 months of age, evenly distributed) obtained from nursery schools, day care centers and civic groups. The data derived from the study were assembled in a meaningful fashion and reviewed to determine whether the packaging met the cited standards for poison prevention packaging presented herein.

III. PROCEDURE

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

Protocol

Code of Federal Regulations Title 16, Part 1700:

1700.20 Testing procedure for testing special packaging.

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

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

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

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

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

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

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

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

year.

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

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

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

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

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

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

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

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

(iii) Sequential test. The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in Table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children

each, up to a maximum of 200 children. No individual shall administer the test to more than 30 percent of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in Table 1 are cumulative.

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

Standardized Child Test Instructions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27. At the end of the test period, the tester shall say, "THANK YOU FOR HELPING." If children

were told that they could use their teeth, the tester shall say, "I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN." In addition, the tester shall say, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

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

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

(3) Senior-adult panel - (i) Test subjects. Use a group of 100 senior adults. Not more than 24 percent of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 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 continuous threaded (CT) plastic closure. Each closure shall have a diameter of 28 mm ∇ 18%, and the CT closures shall have been re-secured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce ∇ ½ ounce for the CT-type closure and 8 drams ∇ 4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

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

interfere with his/her effective participation shall be included in the test.

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

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

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

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

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

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

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and 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 THIS PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

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

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

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

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

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

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

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

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

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

IV. TEST PARAMETERS

The Package

Test package was the **CR Dropper Bottle**. For purposes of this test, all of the units tested were partially filled with water as a placebo. Opening Instructions on closure top panel _
PUSH DOWN WHILE TURNING CLOSE TIGHTLY

Panelists

In the child testing phase of this study, 100 children between the ages of 42 and 51 months distributed into three age groups (42-44, 45-48, and 49-51 months, evenly distributed by sex) were employed. The 100 Bottles used for child testing were previously tested by seniors.

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

Test supervisor(s)

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

PHOTO: CR Dropper Bottle



SPECIFICATIONS/MATERIAL _

Bottle:

Material: Glass

Rubber Bulb: Synthetic Natural Rubber

Overcap/Innercap:

Overcap Material: Polypropylene

Innecap Material: Polyethylene

V. RESULTS AND DISCUSSION

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

- * Child-resistant effectiveness
- * Senior-use effectiveness – Senior Re-closing
- * Meeting current Code of Federal Regulations Title 16, Part 1700.20

Child-resistant effectiveness

Results of the package evaluation by the 100 child panelists appear in Table 1 of the report. From Table 1 it will be noted that 1 of the children opened the package before demonstration and 5 of the children opened the package following demonstration for a total of 6 children successfully able to remove the closure. This represents a child-resistant effectiveness of **94%**

Senior Adult Use Effectiveness

Senior panel consisted of 70 females and 30 males. Results of the senior test appear in Table 2 of this report. A total of 25 of the 25 seniors in the 50 to 54 year old age group were successful in opening and re-closing the first package and opening and properly closing the second package, 25 of the 25 seniors in the 55 to 59 year old age group were successful, and 50 of the 50 seniors were successful in the 60 to 70 year old age group. The SAUE was calculated at **100%**.

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

Wolfgang Enterprise, Inc (FH Packaging)' CR Dropper Bottle Consumer Product Safety Report meets the standards for poison prevention packaging evaluation according to current C.F.R. Title 16, Part 1700.20.

VI. CONCLUSION

The data presented in the report demonstrates that the **CR Dropper Bottle** fulfills the requirements for poison prevention packaging according to the current Code of Federal Regulations Title 16, Part 1700.20.

EVALUATION OF THE **CR DROPPER BOTTLE** AS A CHILD-RESISTANT PACKAGE FOR LIQUID **BOTTLES**

Table 1. Package opening test evaluated by children 42 to 51 months of age for child resistant effectiveness

Age in Months				Successful Panelists				
	Males	Females	Total	Before Demonstration		After Demonstration		Total
				Males	Females	Males	Females	
42-44	14	16	30	1	0	0	0	1
45-48	20	20	40	0	0	0	3	3
49-51	14	16	30	0	0	2	0	2
TOTAL	48	52	100	1	0	2	3	6

CHILD-RESISTANT EFFECTIVENESS = 94%

CHILD DATA: 42 – 44 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	81	43	M		
2.	193	44	M		Turned pulled
3.	108	44	M	4:26	Pulled off top
4.	138	42	M		Pulled on top
5.	126	42	M		
6.	104	43	M		
7.	22	42	M		Squeezed rubber top
8.	15	42	M		Squeezed rubber top
9.	17	44	M		Bent and squeezed rubber stopper
10.	57	44	M		Squeezed rubber top
11.	191	42	M		
12.	109	43	M		

13.	129	42	M		Squeezed rubber top
14.	188	43	M		
15.	97	42	F		
16.	144	43	F		Turned and Pulled off top
17.	21	42	F		Pulled on top
18.	131	43	F		

CHILD DATA: 42 – 44 months continued

	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
19.	42	43	F		Shook/ twisted
20.	79	42	F		Rolled on table
21.	136	43	F		
22.	137	42	F		"What's inside?"
23.	177	43	F		Shook
24.	65	42	F		Squeezed rubber top
25.	10	42	F		
26.	128	43	F		Squeezed rubber top
27.	39	44	F		
28.	107	42	F		Shook bottle. Played with Top
29.	19	42	F		
30.	141	43	F		

CHILD DATA: 45 – 48 months

	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	150	48	M		
2.	73	46	M		Tried to pull and twist
3.	44	45	M		Tried to pull and twist
4.	37	48	M		
5.	70	48	M		Shook bottle.
6.	140	47	M		Wanted me to do it
7.	154	48	M		Pulled real hard

8.	138	48M		Shook/ twisted.
9.	18	45M		Squeezed rubber top
10.	157	47M		
11.	78	47M		Tried to pull off
12.	94	46M		Twisted
13.	38	45M		Shook
14.	178	45M		
15.	69	46M		
16.	72	47M		Squeezed rubber top
17.	83	45M		
18.	88	45M		Shook/twisted/pulled.
19.	175	46M		
20.	156	46M		Wanted a new one.
21.	04	45F		
22.	51	48F	8:32	Pushed and Pulled 'til cap came off
23.	98	46F		Pulled on top
24.	187	45F	9:13	Pulled up twisted off
25.	146	45F		
26.	113	46F	8:12	Pulled off top
27.	11	47F		twisted
28.	162	47F		Pulled on top
29.	26	46F		shook

CHILD DATA: 45 – 48 months continued

	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
30.	192	46F			Squeezed rubber top
31.	77	45F			Wanted me to do for her
32.	95	47F			
33.	169	47F			Squeezed rubber top
34.	96	47F			Squeezed rubber top
35.	115	45F			
36.	176	45F			
37.	30	47F			Twisted top over and over
38.	174	47F			
39.	16	48F			Twisted top/shook.
40.	185	45F			

CHILD DATA: 49 – 51 months

	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	87	49	M		Pulled on top
2.	190	50	M		Squeezed rubber top
3.	193	50	M		Pulled on top
4.	199	49	M		Shook/ twisted and pulled
5.	200	50	M	7:26	Pulled up/ twisted off
6.	33	50	M	5:52	Pulled off

7.	139	50	M		Pulled and twisted rubber top
8.	68	51	M		Turned upside down
9.	161	49	M		Pulled on top
10.	145	49	M		
11.	52	49	M		Squeezed rubber top
12.	151	51	M		
13.	63	50	M		Pulling at the top
14.	56	50	M		Squeezed rubber top
15.	02	50	F		Pulled on top
16.	172	50	F		
17.	102	49	F		Pulled top / twisted
18.	54	49	F		Squeezed rubber top
19.	160	51	F		
20.	186	49	F		
21.	32	49	F		
22.	183	51	F		Shook/ twisted.
23.	31	50	F		
24.	110	50	F		Pulled on top

25	125	51	F		
26	117	50	F		Squeezed rubber top
27	158	51	F		
28	63	50	F		Twisted/ shook
29	185	51	F		Twisted and bent rubber top
30	00	49	F		Squeezed rubber top

EVALUATION OF CR DROPPER BOTTLE REPORT FOR SENIOR ADULT EFFECTIVENESS

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

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

SENIOR-USE EFFECTIVENESS (SAUE) = 100%

ADULT RESECURING 100%

SENIOR ADULT: 50 - 54 YEARS						
	PKG #	PKG #	AGE	GENDER	PASS/FAIL	TIME TO OPEN

1.	148	110	52	M	PASS	:15/:13
2.	198	125	53	M	PASS	:31/:18
3.	66	117	53	M	PASS	:12/:17
4.	119	158	50	M	PASS	:14/:11
5.	100	63	53	M	PASS	:20/:24
6.	118	185	52	M	PASS	:17/:37
7.	143	87	54	M	PASS	:14/:13
8.	101	51	52	M	PASS	:25/:23
9.	20	144	53	F	PASS	:15/:28
10.	114	190	50	F	PASS	:11/:21
11.	08	73	51	F	PASS	:23/:19
12.	116	72	52	F	PASS	:06/:22
13.	53	94	52	F	PASS	:18/:08
14.	54	157	52	F	PASS	:12/:08
15.	13	18	54	F	PASS	:12/:21

SENIOR ADULT: 50 - 54 YEARS continued

	PKG #	PKG #	AGE	GENDER	PASS/FAIL	TIME TO OPEN
16.	55	88	50	F	PASS	1:33/:07
17.	134	83	54	F	PASS	:07/:07
18.	173	69	53	F	PASS	:08/:27
19.	165	178	53	F	PASS	:06/:07
20.	64	38	52	F	PASS	:07/:31
21.	91	78	54	F	PASS	:04/:17
22.	127	16	54	F	PASS	:51/:30

23.	197	43	51	F	PASS	:21/:19
24.	01	11	50	F	PASS	:11/:10
25.	27	02	52	F	PASS	:16/:14

SENIOR ADULT: 55 - 59 YEARS						
	PKG #	PKG #	AGE	GENDER	PASS/FAIL	TIME TO OPEN
1.	21	42	59	M	PASS	:55/:53
2.	196	70	55	M	PASS	:17/:19
3.	116	142	59	M	PASS	:15/:19
4.	14	33	59	M	PASS	:09/:11
5.	05	136	55	M	PASS	:22/:21
6.	43	81	58	M	PASS	:22/:23
7.	41	104	59	M	PASS	:19/:09
8.	182	108	56	M	PASS	:46/:40
9.	89	113	56	F	PASS	:39/:43
10.	147	150	55	F	PASS	:40/:33
11.	76	04	57	F	PASS	:42/:44
12.	88	90	59	F	PASS	:13/:14
13.	84	137	55	F	PASS	:06/:07
14.	82	131	55	F	PASS	:11/:10
15.	194	188	59	F	PASS	:08/:09
16.	48	129	55	F	PASS	:51/:08
17.	112	109	55	F	PASS	:18/:11
18.	06	191	59	F	PASS	:22/:08
19.	49	57	57	F	PASS	:08/:58
20.	24	17	58	F	PASS	:09/:38

21.	60	15	57	F	PASS	:31/:30
22.	07	22	55	F	PASS	:17/:24
23.	40	126	55	F	PASS	:14/:11
24.	179	115	55	F	PASS	:15/:14
25.	111	139	59	F	PASS	:13/:14

SENIOR ADULT: 60 - 70 YEARS						
	PKG #	PKG #	AGE	GENDER	PASS/FAIL	TIME TO OPEN
1.	184	154	63	M	PASS	:22/:16
2.	03	140	63	M	PASS	1:21/:08
3.	67	10	63	M	PASS	:19/:30
4.	47	65	64	M	PASS	:21/:12
5.	124	135	60	M	PASS	:15/:12
6.	35	98	66	M	PASS	:18/:21
7.	153	21	61	M	PASS	:48/:33
8.	09	37	69	M	PASS	:22/:16
9.	142	146	62	M	PASS	:43/:36
10.	36	200	61	M	PASS	:15/:26
11.	75	79	66	M	PASS	1:16/:48
12.	166	156	61	M	PASS	:21/:24
13.	181	199	67	M	PASS	:17/:29
14.	86	26	68	M	PASS	:14/:12
15.	71	96	70	M	PASS	:12/:13
16.	62	138	64	F	PASS	:32/:08
17.	23	97	65	F	PASS	:08/:11
18.	122	144	66	F	PASS	:06/:08
19.	61	141	63	F	PASS	:15/:10
20.	133	19	65	F	PASS	:26/:54
21.	85	107	62	F	PASS	:11/:06
22.	28	39	69	F	PASS	:38/:14
23.	50	128	63	F	PASS	:10/:10

24.	29	177	62	F	PASS	4:18/:07
25.	103	18\	63	F	PASS	:30/:25
26.	168	193	63	F	PASS	:20/:10
27.	45	56	62	F	PASS	:18/:27
28.	165	192	65	F	PASS	:16/:15
29.	99	77	63	F	PASS	:18/:13
30.	145	176	69	F	PASS	:15/:11
31.	106	30	64	F	PASS	:17/:14
32.	169	162	66	F	PASS	:13/:13
33.	189	68	61	F	PASS	:13/:12
34.	164	161	69	F	PASS	:16/:15
35.	14	195	65	F	PASS	:16/:13
36.	131	151	66	F	PASS	:18/:16
37.	140	172	67	F	PASS	:17/:14
38.	152	102	69	F	PASS	:16/:17
39.	170	59	60	F	PASS	:15/:11

SENIOR ADULT: 60 - 70 YEARS continued

	PKG #	PKG #	AGE	GENDER	PASS/FAIL	TIME TO OPEN
40.	123	160	60	F	PASS	:15/:15
41.	163	186	68	F	PASS	:14/:15
42.	74	32	70	F	PASS	:14/:15
43.	92	183	70	F	PASS	:17/:12
44.	171	31	70	F	PASS	:13/:13
45.	120	52	70	F	PASS	:12/:11
46.	180	175	64	F	PASS	:15/:14
47.	155	174	70	F	PASS	:16/:17

48.	159	169	70	F	PASS	:15/:10
49.	80	95	69	F	PASS	:16/:13
50.	201	00	60	F	PASS	:11/:07

GENERAL OBSERVATIONS:

SENIORS

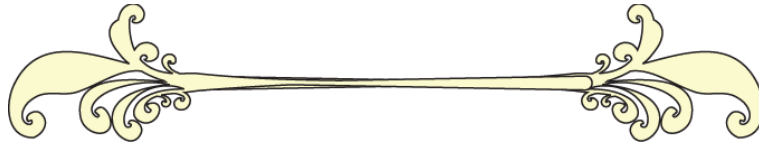
Some of the adults had a few problems opening and re-securing the bottle. For some, the first bottle almost seemed stuck. The one senior that took 4 min had to hit it on the side of the table to loosen. Although no one failed several expressed that it was difficult to open. Protocol went smoothly.

CHILDREN

Those children able to defeat this package did so by pulling very hard on the closure. The inadvertent activity that apparently made removal of the closure somewhat easier than typical was twisting of the outer closure while pulling on it. Children that did not open the bottle concentrating on squeezing the rubber top over and over rather than pulling and twisting.

Test Supervisors

- Debbie Brooks
- Jen Burton
- Julie Ford
- Paige Seriko
- Jeremy Brooks



CERTIFICATION OF COMPLIANCE

IDENTIFICATION of the PRODUCT COVERED by this CERTIFICATE: CR DROPPER BOTTLE

1. Citation to each CPSC product safety regulation to which this product is being certified:
16 CFR Title 16 Part 1700.20

2. Identification of U.S. importer or domestic manufacturer certifying product compliance:
Wolfgang Enterprise, Inc (FH Packaging)
829 S Lemon Ave, Suite A11D
Walnut, CA 91789

3. Contact information for the individual maintaining records of test results:
Gang Wu, Owner
Wolfgang Enterprise, Inc (FH Packaging)
829 S Lemon Ave, Suite A11D
Walnut, CA 91789

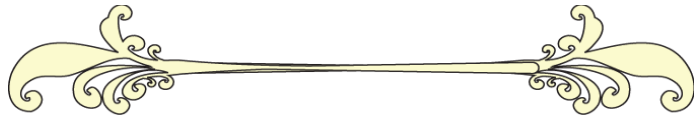
4. Date and place where this product was manufactured:
April 3, 2015
Factory: Yiwu FH Plastics Co. Ltd. (FH Packaging)
No. 2277 Xue Feng West Road
Cheng Xi Street, Yiwu, Zhejiang Province, P. R. C. 322000 China

5. Date and place where product was tested for compliance with regulation(s) cited above:
Testing conducted from June 30, 2015 – July 9, 2015
Bitner Associates, Inc. – Chicago and south, west villages thereof

6. Identification of any third-party facility on whose testing the certificate depends:

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

Results could be used to support Dropper Bottle neck finish sizes from 18-400 20-400 and 22-400 for Boston flint bottle 10ml, 15ml, 30ml, 60ml and 120ml.
when referencing IS08317 bracketing guidelines for CPSIA reasonable testing requirements.



Evaluation of
60ml Boston Round Glass Bottle 20-400 Dropper Closure
as a poison prevention package for
Wolfgang Enterprise, INC
DBA: FH Packaging

by

Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, Illinois 60554



Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL
60554
Ph. 708.738.5598

July 16, 2016

Wolfgang Enterprise, INC
DBA: FH Packaging
902 Columbia Ave
Riverside, CA 92507

Attention: Gang Wu;
Herein is our report **60ml Glass Bottle 20-400 Dropper Closure** as a Poison Protection
Package.

The test units were evaluated using the Consumer Product Safety Commission Protocol and Standards. Study indicates **60ml Glass Bottle 20-400 Closure** fulfills requirements for a Poison Prevention Package as per the current Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Sincerely,
BITNER ASSOCIATES, Inc.



John Bitner
President

Child-Resistant Package Testing • Design • Development

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I. SUMMARY

Report to: Wolfgang Enterprise, INC
DBA: FH Packaging
902 Columbia Ave
Riverside, CA 92507

Samples of: **60ml Boston Round Glass Bottle 20-400 Closure**

Contract No.: 1371-285
Samples Received: July 11, 2016
Submitted by: Gang Wu

Objective

Wolfgang Enterprises, INC submitted the **60ml Glass Bottle 20-400 Dropper Closure** to determine if the bottle/closure would be compliant with the Consumer Product Safety Commission's current protocol and standards for poison prevention packaging Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Procedures

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

Panelists

In the course of this study 100 children (42 to 51 months of age) and 100 seniors (50 to 70 year-olds, 70% female) were employed.

Results

Results of the study indicate that the **60 ml Glass Bottle 20-400 Closure** meets the standards for poison prevention packaging according to current C.F.R. Title 16 Part 1700.20.

II. INTRODUCTION

Wolfgang Enterprises wished to determine if the **60 ml Glass Bottle 20-400 Closure** fulfills Consumer Product Safety Commission's (CPSC) current standards and protocol for poison prevention packaging set forth in Code of Federal Regulations Title 16, Part 1700.20. Bitner Associates is recognized testing laboratory facility for testing child-resistant packaging according to CPSC protocol. They were requested to evaluate this package using the above mentioned protocol.

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

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

III. PROCEDURE

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

Protocol

Code of Federal Regulations Title 16, Part 1700:

1700.20 Testing procedure for testing special packaging.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) Test procedures. The children shall be divided into groups of two. The testing shall

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

Standardized Child Test Instructions

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

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

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

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

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

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

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

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

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

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

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversations with the

children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., "please try to open the package").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) Senior-adult panel - (i) Test subjects. Use a group of 100 senior adults. Not more than 24 percent of the senior adults tested shall be obtained from or tested at any one site. Each

group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 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 continuous threaded (CT) plastic closure. Each closure shall have a diameter of 28 mm ± 18%, and the CT closures shall have been re-secured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce ± ½ ounce for the CT-type closure and 8 drams ± 4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly 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 which would interfere with his/her effective participation shall be included in the test.
2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.
3. Each adult shall participate individually and not in the presence of other participants or onlookers.
4. The tests shall be conducted in well-lighted and distraction-free areas.
5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the packages are the only exceptions.
6. To begin the first 5-minute test period, the tester says, "I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP." (Specify other instruction locations if appropriate.)
7. The first package is handed to the participant by the tester, who says, "PLEASE OPEN

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

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and 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 THIS PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

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

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

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

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

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

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

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

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

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

IV. TEST PARAMETERS

The Package

Test package was **60 ml Glass Bottle 20-400 Dropper Closure**. For purposes of this test, all units tested were partially filled with water.

The Push and Turn CR feature was considered intuitive. No written opening and re-securing instructions were given.

Panelists

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

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

Test supervisor(s)

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

PHOTO: 60ml Boston Round Glass Bottle 20-400 Dropper Closure



Specifications:

Bottle: 60ml Boston Round Glass
Closure: 20mm/400 Dropper Closure
Outer Cap: Polypropylene, black
Inner Cap: Polypropylene, natural
Pipette: Glass

V. RESULTS AND DISCUSSION

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

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

Child-resistant effectiveness

Results of the package evaluation by the 100 child panelists aged 42-51 months appear in Table 1 of the report. From Table 1 it will be noted that none of the children opened the package before demonstration and none of the children were able to remove the closure following demonstration for a total of 0 successful child panelists. This represents a child-resistant effectiveness of **100%**.

Senior Adult Use Effectiveness

Senior panel consisted of 70 females and 30 males. Results of the senior test appear in Table 2 of this report. A total of 25 of the 25 seniors in the 50 to 54-year-old age group were successful in opening the first package and opening and properly closing the second package, 25 of the 25 seniors in the 55 to 59-year-old age group were successful, and 50 of the 50 seniors were successful in the 60 to 70-year-old age group. The SAUE was calculated at **100%**.

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

Liquid Bottles **60 ml Glass Bottle 20-400 Closure** Consumer Product Safety Report meets the standards for poison prevention packaging evaluation per current C.F.R. Title 16, Part 1700.02.

CONCLUSION

Data presented in report demonstrates that the **60ml Glass Bottle 20-400 Closure** meets requirements for poison prevention packaging according to the current Code of Federal Regulations Title 16, Part 1700.20. Package performed very well for senior adults and only one child was able to defeat it.

EVALUATION OF 60ml Glass Bottle 20-400 Closure AS A CHILD-RESISTANT PACKAGE

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

Age in Months	Males	Females	Total	Successful Panelists		Males	Females	Total
				Before Demonstration	After Demonstration			
42-44	14	16	30	0	0	0	0	0
45-48	20	20	40	0	0	0	0	0
49-51	14	16	30	0	0	0	0	0
TOTAL	50	50	100	0	0	0	0	0

CHILD-RESISTANT EFFECTIVENESS = 100%

CHILD DATA: 42 – 44 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	72	43	M		Played with top
2.	74	42	M		Pulled/Twisted
3.	76	44	M		Played with top
4.	78	42	M		Played with top
5.	80	43	M		
6.	82	42	M		Twisted/Shook
7.	84	43	M		
8.	86	42	M		
9.	88	44	M		Pulled/Twisted
10.	90	44	M		
11.	92	42	M		Played with bottle

12.	94	42	M		
13.	96	42	M		Twisted, Shook
14.	98	44	M		Bit on Top
15.	100	43	F		Played with top

CHILD DATA: 42 – 44 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
16.	42	42	F		Played with top
17.	44	43	F		
18.	46	42	F		Played with top
19.	48	43	F		Played with closure
20.	50	42	F		Played with top
21.	52	42	F		
22.	54	42	F		Twisted
23.	56	44	F		Tried to pull off
24.	58	43	F		Twisted continuously
25.	60	42	F		Pulled on top
26.	62	44	F		Twisted cap
27.	64	42	F		
28.	66	43	F		Played with top
29.	68	44	F		
30.	70	42	F		Twisted repeatedly

CHILD DATA: 45 – 48 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	2	47	M		
2.	4	45	M		Played with top
3.	6	47	M		
4.	8	49	M		Twisted and twisted
5.	10	47	M		Played with top
6.	12	45	M		Played with top
7.	14	46	M		
8.	16	47	M		Pulled on top
9.	18	48	M		
10.	20	46	M		Twisted cap
11.	22	45	M		Played with top

12.	24	47	M		
13.	26	45	M		Tried to pull top off
14.	28	48	M		
15.	30	47	M		Continued to twist
16.	32	45	M		Tried to pull off the top
17.	34	46	M		Twisted cap
18.	36	46	M		Played with top
19.	38	45	M		Pulled real hard
20.	40	47	M		Twisted

CHILD DATA: 45 – 48 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
21	162	48	F		Played with top
22.	164	48	F		Twisted
23.	166	46	F		
24.	168	48	F		
25.	170	46	F		Played with top
26.	172	48	F		Twisted cap
27.	174	48	F		Twisted
28.	176	46	F		
29.	178	46	F		Twisted
30.	180	46	F		
31.	182	45	F		Shook, twisted
32.	184	45	F		Twisted the top
33.	186	48	F		Shook, twisted
34.	188	47	F		
35.	190	48	F		Played with bottle
36.	192	48	F		
37.	194	48	F		Played with top
38.	196	50	F		Twisted top
39.	198	48	F		Pulled on top
40.	200	48	F		Twisted over and over

CHILD DATA: 49 – 51 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	132	50	M		Played with top
2.	134	49	M		Played with top
3.	136	49	M		
4.	138	50	M		

5.	140	51	M		Twisted cap
6.	142	51	M		Kept pulling on top
7.	144	50	M		
8.	146	49	M		Played with top
9.	148	49	M		
10	150	49	M		Twisted over and over
.					
11	152	51	M		Shook, twisted
.					
12	154	50	M		
.					
13	156	51	M		Played with top
.					
14	158	49	M		Tried to pull it off
.					
15	160	51	F		
.					

CHILD DATA: 49 – 51 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
16 .	102	49	F		Twisted top
17 .	104	51	F		Twisted
18 .	106	50	F		Played with top
19 .	108	51	F		Played with top
20 .	110	50	F		Played with top
21 .	112	50	F		Put in mouth
22 .	114	51	F		Twisted
23 .	116	50	F		
24 .	118	50	F		Tried to pull off the top
25 .	120	51	F		
26 .	122	49	F		Twisted, played with top
27 .	124	49	F		
28 .	126	50	F		
29 .	128	51	F		
30 .	130	49	F		Twisted

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EVALUATION OF FOR 60ml Glass Bottle 20-400 Closure SENIOR EFFECTIVENESS

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

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

**SENIOR-USE EFFECTIVENESS (SAUE) = 100%
100%**

ADULT RESECURING

SENIOR ADULT: 50 – 54 YEARS						
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
1.	151	152	53	M	PASS	:07/:03
2.	153	154	53	M	PASS	:06/:03
3.	155	156	50	M	PASS	:06/:07
4.	157	158	50	M	PASS	:06/:07
5.	159	160	50	M	PASS	:07/:06
6.	161	162	50	M	PASS	:15/:09

7.	163	164	52	M	PASS	:10/:07
8.	165	166	53	M	PASS	:11/:09
9.	167	168	53	F	PASS	:10/:08
10.	169	170	52	F	PASS	:11/:10
11.	171	172	51	F	PASS	:11/:07
12.	173	174	53	F	PASS	:12/:09
13.	175	176	50	F	PASS	:09/:08
14.	177	178	54	F	PASS	:16/:25
15.	179	180	50	F	PASS	:08/:09
16.	181	182	54	F	PASS	:09/:06
17.	183	184	52	F	PASS	:15/:08
18.	185	186	51	F	PASS	:06/:09
19.	187	188	50	F	PASS	:10/:10
20.	189	190	52	F	PASS	:12/:09
21.	191	192	53	F	PASS	:12/:11
22.	193	194	50	F	PASS	:11/:10
23.	195	196	52	F	PASS	:13/:10
24.	197	198	51	F	PASS	:15/:10
25.	199	200	54	F	PASS	:12/:10

SENIOR ADULT: 55 – 59 YEARS						
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
1.	101	102	56	M	PASS	:12/:09
2.	103	104	57	M	PASS	:13/:08

3.	105	106	55	M	PASS	:11/:09
4.	107	108	55	M	PASS	:13/:09

SENIOR ADULT: 55 – 59 YEARS continued						
5.	109	110	59	M	PASS	:15/:10
6.	111	112	57	M	PASS	:12/:09
7.	113	114	55	M	PASS	:10/:11
8.	115	116	57	M	PASS	:07/:06
9.	117	118	57	F	PASS	:08/:12
10.	119	120	55	F	PASS	:06/:09
11.	121	122	59	F	PASS	:12/:09
12.	123	124	59	F	PASS	:12/:09
13.	125	126	56	F	PASS	:04/:03
14.	127	128	56	F	PASS	:04/:10
15.	129	130	55	F	PASS	:06/:13
16.	131	132	55	F	PASS	:14/:16
17.	133	134	56	F	PASS	:13/:09
18.	135	136	59	F	PASS	:12/:10
19.	137	138	57	F	PASS	:12/:15
20.	139	140	56	F	PASS	:06/:28
21.	141	142	58	F	PASS	:07/:07
22.	143	144	55	F	PASS	:07/:08
23.	145	146	56	F	PASS	:08/:06
24.	147	148	55	F	PASS	:11/:12
25.	149	150	58	F	PASS	:10/:15

SENIOR ADULT: 60 - 70 YEARS

	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
1.	01	02	70	M	PASS	:03/:12
2.	03	04	67	M	PASS	:06/:05
3.	05	06	67	M	PASS	:08/:12
4.	07	08	60	M	PASS	:07/:05
5.	09	10	67	M	PASS	:05/:07
6.	11	12	68	M	PASS	:06/:05
7.	13	14	70	M	PASS	:04/:07
8.	15	16	66	M	PASS	:10/:07
9.	17	18	66	M	PASS	:12/:09
10.	19	20	62	M	PASS	:10/:08
11.	21	22	61	M	PASS	:12/:09
12.	23	24	60	M	PASS	:14/:09
13.	25	26	68	M	PASS	:13/:09

SENIOR ADULT: 60 - 70 YEARS continued						
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
14.	27	28	68	M	PASS	:09/:10
15.	29	30	67	M	PASS	:08/:08
16.	31	32	60	F	PASS	:13/:09
17.	33	34	62	F	PASS	:09/:06
18.	35	36	65	F	PASS	:12/:06
19.	37	38	68	F	PASS	:11/:08
20.	39	40	66	F	PASS	:10/:06
21.	41	42	70	F	PASS	:16/:10
22.	43	44	64	F	PASS	:11/:06
23.	45	46	61	F	PASS	:08/:06
24.	47	48	63	F	PASS	:10/:06
25.	49	50	69	F	PASS	:04/:06
26.	51	52	60	F	PASS	:13/:10
27.	53	54	65	F	PASS	:07/:09
28.	55	56	70	F	PASS	:08/:10
29.	57	58	62	F	PASS	:07/:09
30.	59	60	61	F	PASS	:10/:09
31.	61	62	63	F	PASS	:13/:09
32.	63	64	66	F	PASS	:07/:06
33.	65	66	62	F	PASS	:10/:09
34.	67	68	68	F	PASS	:12/:13
35.	69	70	70	F	PASS	:09/:13

36.	71	72	64	F	PASS	:13/:10
37.	73	74	61	F	PASS	:12/:10
38.	75	76	60	F	PASS	:13/:09
39.	77	78	60	F	PASS	:12/:11
40.	79	80	66	F	PASS	:13/:09
41.	81	82	70	F	PASS	:08/:11
42.	83	84	62	F	PASS	:12/:09
43.	85	86	60	F	PASS	:13/:10
44.	87	88	70	F	PASS	:13/:09
45.	89	90	70	F	PASS	:10/:12
46.	91	92	66	F	PASS	:12/:10
47.	93	94	60	F	PASS	:13/:09
48.	95	96	61	F	PASS	:13/:10
49.	97	98	60	F	PASS	:13/:09
50.	99	100	68	F	PASS	:11/:10

GENERAL OBSERVATIONS:

SENIORS

Seniors had no difficulty opening and re-securing the bottle. No negative feedback about this Glass Bottle/Dropper Closure.

CHILDREN

The children loved to play with the back rubber tip of the bottle. They pushed it in, they bit on it, and they snapped it. I think the fact that they play with the rubber stopper distracts them from trying to open the bottle with little interest from what is inside of it.

Test Supervisors

- ! Debbie Brooks
- ! Julie Ford
- ! Jeremy Brooks
- ! Jen Burton
- ! Raechel Buckner

Evaluation of
120ml Glass Boston Round Bottle 22-400
as a poison prevention package for
Wolfgang Enterprise, INC
DBA: FH Packaging

by

Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, Illinois 60554



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

July 16, 2016

Wolfgang Enterprise, INC
DBA: FH Packaging
902 Columbia Ave
Riverside, CA 92507

Attention: Gang Wu;
Herein is our report **120ml Glass Boston Round Bottle 22-400** as a Poison Protection Package.

The test units were evaluated using the Consumer Product Safety Commission Protocol and Standards. Study indicates **120ml Glass Boston Round Bottle 22-400** fulfills requirements for a Poison Prevention Package as per the current Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Sincerely,
BITNER ASSOCIATES, Inc.



John Bitner
President

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I. SUMMARY

Report to: Wolfgang Enterprise, INC
DBA: FH Packacing
902 Columbia Ave.
Riverside, CA 92507

Samples of: **120ml Glass Boston Round Bottle 22mm-400 Closure**

Contract No.: 1371-285
Samples Received: July 11, 2016
Submitted by: Gang Wu

Objective

Wolfgang Enterprise, INC. submitted **120ml Glass Boston Round Bottle 22-400 Closure** to determine if the bottle/closure would be compliant with the Consumer Product Safety Commission's current protocol and standards for poison prevention packaging Code of Federal Regulations (C.F.R.) Title 16, Part 1700.20.

Procedures

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

Panelists

In the course of this study 100 children (42 to 51 months of age) and 100 seniors (50 to 70 year-olds, 70% female) were employed.

Results

Results of the study indicate that the **120ml Glass Boston Round Bottle 22mm/400** meets the standards for poison prevention packaging according to current C.F.R. Title 16 Part 1700.20.

II. INTRODUCTION

Wolfgang Enterprise, INC wished to determine if the **120ml Glass Boston Round Bottle 22-400** fulfills Consumer Product Safety Commission's (CPSC) current standards and protocol for poison prevention packaging set forth in Code of Federal Regulations Title 16, Part 1700.20. Bitner Associates is recognized testing laboratory facility for testing child-resistant packaging according to CPSC protocol. They were requested to evaluate this package using the above mentioned protocol.

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

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

III. PROCEDURE

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

Protocol

Code of Federal Regulations Title 16, Part 1700:

1700.20 Testing procedure for testing special packaging.

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

(ii) Condition of packages to be tested. (A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to

the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies.

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

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

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

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

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

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

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

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

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

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

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

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

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

Office of Compliance.

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

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

Standardized Child Test Instructions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27. At the end of the test period, the tester shall say, "THANK YOU FOR HELPING." If children were told that they could use their teeth, the tester shall say, "I KNOW I TOLD YOU THAT

YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN." In addition, the tester shall say, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

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

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

(3) Senior-adult panel - (i) Test subjects. Use a group of 100 senior adults. Not more than 24 percent of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 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 continuous threaded (CT) plastic closure. Each closure shall have a diameter of 28 mm ! 18%, and the CT closures shall have been re-secured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce ! ½ ounce for the CT-type closure and 8 drams ! 4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly 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 which would interfere with his/her effective participation shall be included in the test.

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

participate in the test.

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

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

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

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

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

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and 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 THIS PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

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

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

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

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

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

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

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

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

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

IV. TEST PARAMETERS

The Package

Test package was **120ml Glass Bottle 22mm-400**. For purposes of this test, all units tested were partially filled with water.

The Push and Turn CR feature was considered intuitive. No written opening and re-securing instructions were given.

Panelists

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

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

Test supervisor(s)

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

PHOTO: 120ml Glass Boston Round Bottle 22-400



Specifications:

Bottle: 120ml Glass

Caps: 22mm/400

Outer Cap: Polypropylene

Inner Cap: Polypropylene

V. RESULTS AND DISCUSSION

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

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

Child-resistant effectiveness

Results of the package evaluation by the 100 child panelists aged 42-51 months appear in Table 1 of the report. From Table 1 it will be noted that three of the children opened the package before demonstration and 4 children were able to remove the closure following demonstration for a total of 7 successful child panelists. This represents a child-resistant effectiveness of **93%**.

Senior Adult Use Effectiveness

Senior panel consisted of 70 females and 30 males. Results of the senior test appear in Table 2 of this report. A total of 25 of the 25 seniors in the 50 to 54-year-old age group were successful in opening the first package and opening and properly closing the second package, 25 of the 25 seniors in the 55 to 59-year-old age group were successful, and 50 of the 50 seniors were successful in the 60 to 70-year-old age group. The SAUE was calculated at **100%**.

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

Liquid Bottles **120ml Glass Boston Round Bottle 22-400** Consumer Product Safety Report meets the standards for poison prevention packaging evaluation per current C.F.R. Title 16, Part 1700.02.

CONCLUSION

Data presented in report demonstrates that the **120ml Glass Boston Round Bottle 22-400** meets requirements for poison prevention packaging according to the current Code of Federal Regulations Title 16, Part 1700.20. Package performed very well for senior adults and only one child was able to defeat it.

EVALUATION OF 120ml Glass Boston Round Bottle 22-400 AS A CHILD-RESISTANT PACKAGE

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

Age in Months	Males	Females	Total	Successful Panelists		Males	Females	Total
				Before Demonstration	After Demonstration			
42-44	14	16	30	0	0	0	0	0
45-48	20	20	40	1	0	1	0	2
49-51	14	16	30	2	0	0	3	5
TOTAL	50	50	100	3	0	1	3	7

CHILD-RESISTANT EFFECTIVENESS = 93%

CHILD DATA: 42 – 44 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	2	43	M		Played with rubber top
2.	4	42	M		Pulled/Twisted
3.	6	44	M		Played with rubber top
4.	8	42	M		Played with rubber top
5.	10	43	M		
6.	12	42	M		Twisted/Shook
7.	14	43	M		
8.	16	42	M		
9.	18	44	M		Pulled/Twisted
10.	20	44	M		
11.	22	42	M		Played with bottle

12.	24	42	M		
13.	26	42	M		Twisted, Shook
14.	28	44	M		Bit on Top
15.	30	43	F		Played with rubber top

CHILD DATA: 42 – 44 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
16.	32	42	F		Played with rubber top
17.	34	43	F		
18.	36	42	F		Played with rubber top
19.	38	43	F		Played with closure
20.	40	42	F		Played with rubber top
21.	42	42	F		
22.	44	42	F		Twisted
23.	46	44	F		Tried to pull off
24.	48	43	F		Twisted continuously
25.	50	42	F		Pulled on top
26.	52	44	F		Twisted cap
27.	54	42	F		
28.	56	43	F		Played with rubber top
29.	58	44	F		
30.	60	42	F		Twisted repeatedly

CHILD DATA: 45 – 48 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	62	47	M	4:12	Pulled hard came off
2.	64	45	M		Played with rubber top
3.	66	47	M		
4.	68	49	M		Twisted and twisted
5.	70	47	M		Played with rubber top
6.	72	45	M		Played with rubber top
7.	74	46	M		
8.	76	47	M		Pulled on top
9.	78	48	M		
10.	80	46	M		Twisted cap
11.	82	45	M		Played with rubber top

12.	84	47	M		
13.	86	45	M		Tried to pull top off
14.	88	48	M	8:36	Twisted and pulled off
15.	90	47	M		Continued to twist
16.	92	45	M		Tried to pull off the top
17.	94	46	M		Twisted cap
18.	96	46	M		Played with top
19.	98	45	M		Pulled real hard
20.	100	47	M		Twisted

CHILD DATA: 45 – 48 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
21	102	48	F		Played with rubber top
22.	104	48	F		Twisted
23.	106	46	F		
24.	108	48	F		
25.	110	46	F		Played with rubber top
26.	112	48	F		Twisted cap
27.	114	48	F		Twisted
28.	116	46	F		
29.	118	46	F		Twisted
30.	120	46	F		
31.	122	45	F		Shook, twisted
32.	124	45	F		Twisted the top
33.	126	48	F		Shook, twisted
34.	128	47	F		
35.	130	48	F		Played with bottle
36.	132	48	F		
37.	134	48	F		Played with rubber top
38.	136	50	F		Twisted top
39.	138	48	F		Pulled on top
40.	140	48	F		Twisted over and over

CHILD DATA: 49 – 51 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	142	50	M		Played with rubber top
2.	144	49	M		Played with rubber top
3.	146	49	M	2:82	Twisted and pulled off
4.	148	50	M	4:36	Pulled Off Top

5.	150	51	M		Twisted cap
6.	152	51	M		Kept pulling on top
7.	154	50	M		
8.	156	49	M		Played with rubber top
9.	158	49	M		
10	160	49	M		Twisted over and over
.					
11	162	51	M		Shook, twisted
.					
12	164	50	M		
.					
13	166	51	M		Played with rubber top
.					
14	168	49	M		Tried to pull it off
.					
15	170	51	F		
.					

CHILD DATA: 49 – 51 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
16 .	172	49	F		Twisted top
17 .	174	51	F		Twisted
18 .	176	50	F		Played with rubber top
19 .	178	51	F		Played with rubber top
20 .	180	50	F		Played with rubber top
21 .	182	50	F		Put in mouth
22 .	184	51	F		Twisted
23 .	186	50	F		
24 .	188	50	F		Tried to pull off the top
25 .	190	51	F		
26 .	192	49	F		Twisted, played with top
27 .	194	49	F	5:64	Pulled off top
28 .	196	50	F	7:18	Pulled really hard
29 .	198	51	F	7:36	Pulled really hard
30 .	200	49	F		Twisted

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EVALUATION OF FOR 120ml Glass Boston Round Bottle 22-400 SENIOR EFFECTIVENESS

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

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

**SENIOR-USE EFFECTIVENESS (SAUE) = 100%
100%**

ADULT RESECURING

SENIOR ADULT: 50 – 54 YEARS						
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
1.	99	100	51	M	PASS	:14/:12
2.	101	102	53	M	PASS	:11/:09
3.	103	104	53	M	PASS	:13/:11
4.	105	106	54	M	PASS	:12/:10
5.	107	108	54	M	PASS	:13/:09
6.	109	110	52	M	PASS	:15/:12

7.	111	112	50	M	PASS	:12/:09
8.	113	114	52	M	PASS	:06/:07
9.	115	116	51	F	PASS	:08/:06
10.	117	118	53	F	PASS	:06/:04
11.	119	120	53	F	PASS	:15/:12
12.	121	122	50	F	PASS	:05/:04
13.	123	124	54	F	PASS	:04/:10
14.	125	126	54	F	PASS	:13/:13
15.	127	128	50	F	PASS	:12/:14
16.	129	130	54	F	PASS	:13/:09
17.	131	132	52	F	PASS	:15/:08
18.	133	134	51	F	PASS	:06/:09
19.	135	136	50	F	PASS	:10/:10
20.	137	138	52	F	PASS	:12/:09
21.	139	140	53	F	PASS	:12/:11
22.	141	142	50	F	PASS	:11/:10
23.	143	144	52	F	PASS	:13/:10
24.	145	146	51	F	PASS	:15/:10
25.	147	148	54	F	PASS	:12/:10

SENIOR ADULT: 55 – 59 YEARS						
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
1.	149	150		M	PASS	:12/:09
2.	151	152		M	PASS	:13/:08

3.	153	154		M	PASS	:11/:09
4.	155	156		M	PASS	:13/:09

SENIOR ADULT: 55 – 59 YEARS continued						
5.	157	158	59	M	PASS	:15/:10
6.	159	160	57	M	PASS	:12/:09
7.	161	162	55	M	PASS	:10/:11
8.	163	164	57	M	PASS	:07/:06
9.	165	166	57	F	PASS	:08/:12
10.	167	168	55	F	PASS	:06/:09
11.	169	170	59	F	PASS	:12/:09
12.	171	172	59	F	PASS	:12/:09
13.	173	174	56	F	PASS	:04/:03
14.	175	176	56	F	PASS	:04/:10
15.	177	178	55	F	PASS	:06/:13
16.	179	180	55	F	PASS	:14/:16
17.	181	182	56	F	PASS	:13/:09
18.	183	184	59	F	PASS	:12/:10
19.	185	186	57	F	PASS	:12/:15
20.	187	188	56	F	PASS	:06/:28
21.	189	190	58	F	PASS	:07/:07
22.	191	192	55	F	PASS	:07/:08
23.	193	194	56	F	PASS	:08/:06
24.	195	196	55	F	PASS	:11/:12
25.	197	198	58	F	PASS	:10/:15

SENIOR ADULT: 60 - 70 YEARS

	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
1.	01	02		M	PASS	:07/:06
2.	03	04		M	PASS	:10/:08
3.	05	06		M	PASS	:11/:12
4.	07	08		M	PASS	:10/:09
5.	09	10		M	PASS	:12/:09
6.	11	12		M	PASS	:08/:06
7.	13	14		M	PASS	:14/:08
8.	15	16		M	PASS	:05/:04
9.	17	18		M	PASS	:12/:08
10.	19	20		M	PASS	:17/08
11.	21	22		M	PASS	:05/:05
12.	23	24		M	PASS	:13/:09
13.	25	26		M	PASS	:14/:08

SENIOR ADULT: 60 - 70 YEARS continued						
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	5min/1min Times To Open
14.	27	28	60	M	PASS	:14/:09
15.	29	30	62	M	PASS	:08/:08
16.	31	32	62	F	PASS	:08/:11
17.	33	34	66	F	PASS	:07/:10
18.	35	36	67	F	PASS	:06/:10
19.	37	38	65	F	PASS	:08/:10
20.	39	40	69	F	PASS	:10/:11
21.	41	42	68	F	PASS	:09/:12
22.	43	44	60	F	PASS	:08/:11
23.	45	46	66	F	PASS	:09/:11
24.	47	48	68	F	PASS	:07/:10
25.	49	50	61	F	PASS	:08/:10
26.	51	52	60	F	PASS	:13/:10
27.	53	54	65	F	PASS	:07/:09
28.	55	56	70	F	PASS	:08/:10
29.	57	58	62	F	PASS	:07/:09
30.	59	60	61	F	PASS	:10/:09
31.	61	62	63	F	PASS	:13/:09
32.	63	64	66	F	PASS	:07/:06
33.	65	66	62	F	PASS	:10/:09
34.	67	68	68	F	PASS	:12/:13
35.	69	70	70	F	PASS	:09/:13

36.	71	72	64	F	PASS	:13/:10
37.	73	74	61	F	PASS	:12/:10
38.	75	76	60	F	PASS	:13/:09
39.	77	78	60	F	PASS	:12/:11
40.	79	80	66	F	PASS	:13/:09
41.	81	82	70	F	PASS	:08/:11
42.	83	84	62	F	PASS	:12/:09
43.	85	86	60	F	PASS	:13/:10
44.	87	88	70	F	PASS	:13/:09
45.	89	90	70	F	PASS	:10/:12
46.	91	92	66	F	PASS	:12/:10
47.	93	94	60	F	PASS	:13/:09
48.	95	96	61	F	PASS	:13/:10
49.	97	98	60	F	PASS	:13/:09
50.	199	200	68	F	PASS	:11/:10

GENERAL OBSERVATIONS:

SENIORS

For the most part, adults had no problem opening and re-closing the bottle. Some had a difficult time pushing down on the cap. Overall they liked the bottle.

CHILDREN

The children played with the rubber stopper. They twisted the bottle and pulled real hard. Some of the children gained access by pulling very hard on the top, of the seven children that got in only one child did so by twisted and pulling.

Test Supervisors

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- ! Julie Ford
- ! Jeremy Brooks
- ! Jen Burton
- ! Jamie Rakowski