

# CRC Certification Disclaimer

Please be advised that our child resistant closures have been tested and found to be in compliance with 16 CFR 1700 as evidenced in the enclosed certification. While they are capable of passing CR testing with your packaging, we cannot control the application torque, re-torque, bottle used, or any product on the finish. Therefore, it is YOUR responsibility to test YOUR total package.

Sincerely,

Hunter Holton

Kuto Vitter

Vice President

Never Pay Retail Again, Inc.

d/b/a Glass Bottle Outlet

### Evaluation of

# 120ml Bottle 22/400 Dropper Closure

as a poison prevention package for Never Pay Retail Again, Inc. d/b/a **Glass Bottle Outlet** 

By

Bitner Associates, Inc.

1001 Forest Trail Sugar Grove, Illinois 60554



May 16, 2016

Glass Bottle Outlet 3029 US 27 North Sebring, FL 33870

Attention: Mary Bengston

Herein is our report titled **120ml Bottle 22/400 Closure** as a Poison Protection Package for **Glass Bottle Outlet.** 

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

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

Sincerely,

BITNER ASSOCIATES, Inc.

John Bitner President

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### I. SUMMARY

Report to:

Glass Bottle Outlet 3029 US 27 North Sebring, FL 33870

Date: May 16, 2016

Samples of: 120ml Bottle 22/400 Closure

Contract No.: 1371-191
Samples Received: May19, 2016
Submitted by: Mary Bengston

### **Objective**

Glass Bottle Outlet submitted the 120ml Bottle 22/400 Dropper Closure for a study to determine if bottle/closure is in compliance with 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 120ml Glass Bottle-22/400mm Dropper Closure meets **the standards for poison prevention packaging** according to current C.F.R. Title 16, Part 1700.20.

### II. INTRODUCTION

Glass Bottle Outlet wished to determine if the 120ml Bottle 22/400 Closure 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.)

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	Cumulative	Package Openings						
Panel	number of	]	First 5 minutes	3	F	Full 10 minutes		
	children	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+	

- (ii) Test failures. A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units 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  $\forall$  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  $\forall$  ½ ounce for the CT-type closure and 8 drams  $\forall$  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 resecuring times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.
- 9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying skip to Instruction 13.
- 10. To begin the second test period, the tester shall give the participant another, but identical, package and say, "THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE 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 Bottle 22/400 Closure.** For purposes of this test, all 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: 120ml Bottle 22/400 Dropper Closure



## SPECIFICATIONS \_

Bottle: 120ml Glass

Pipette: Glass Length: 108mm Dropper: Synthetic Rubber

Overcap: 22/400mm Polypropylene Innercap: 22/400mm 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 120ml Bottle 22/400 Closure evaluation by 100 child panelists 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 opened the package following demonstration for a total of 0 children successfully able to remove closure. Child-resistant effectiveness is 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 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.

**120ml Bottle 22/400 Closure** 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**

Data presented in this report demonstrates that **120ml Bottle 22/400 Closure** fulfills requirements for poison prevention packaging according to the current Code of Federal Regulations Title 16, Part 1700.20.

# EVALUATION OF THE 120ML BOTTLE 22/400 CLOSURE AS A $\underline{\text{CHILD-RESISTANT}}$ PACKAGE FOR GLASS BOTTLE OUTLET

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

					Successful	Panelist	S	
					efore nstration		After Instration	
Age in								
Months	Males	Females	Total	Males	Females	Males	Females	Total
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	48	52	100	0	0	0	0	0

### **CHILD-RESISTANT EFFECTIVENESS = 100%**

CHILD	CHILD DATA: 42 – 44 months								
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS				
1.	02	42	M		Squeezed the stopper				
2.	04	42	M		Pick at the top				
3.	06	42	M		Shook the bottle				
4.	08	42	M						
5.	10	42	M						
6.	12	42	M		Shook bottle				
7.	14	43	M		"you have to turn it backward"				
8.	16	44	M		"when is snack time"				
9.	18	42	M		Pulled on top				
10.	20	42	M		Twisted cap				
11.	22	43	M						
12.	24	42	M		Squeezed rubber top				
13.	26	42	M						
14.	28	42	M		Played with rubber stopper				
15.	30	43	F						
16.	32	43	F		Rolled bottle				
17.	34	42	F						
18.	36	44	F		Played with rubber stopper				

CHILD	CHILD DATA: 42 – 44 months continued								
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS				
19.	38	42	F						
20.	40	44	F						
21.	42	44	F		Played with rubber stopper				
22.	44	44	F		Pulled on top				
23.	46	43	F						
24.	48	42	F		Kept twisting				
25.	50	42	F		Played with rubber stopper				
26.	52	42	F		Bit on top				
27.	54	44	F						
28.	56	42	F		Tried to pull it off				
29.	58	43	F						
30.	60	42	F		Played with rubber stopper				

CHILD	DATA: 4	5 - 48  m	onths		
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	62	48	M		Played with rubber stopper
2.	64	45	M		Shook/twisted
3.	66	46	M		
4.	68	45	M		Played with rubber stopper
5.	70	46	M		
6.	72	45	M		Twisted cap
7.	74	48	M		Played with rubber stopper
8.	76	48	M		
9.	78	46	M		Put in mouth tried to use teeth
10.	80	45	M		Played with rubber stopper
11.	82	46	M		Played with bottle
12.	84	47	M		
13.	86	45	M		Twisted the top
14.	88	45	M		Played with rubber stopper
15.	90	45	M		
16.	92	45	M		Played with rubber stopper
17.	94	45	M		Wanted to know why
18.	96	45	M		
19.	98	45	M		Played with rubber stopper
20.	100	45	M		Pulled and bit on top
21.	102	45	F		Twisted
22.	104	45	F		
23.	106	45	F		Put in mouth
24.	108	46	F		
25.	110	48	F		
26.	112	48	F		Shook and twisted
27.	114	47	F		
28.	116	47	F		Pulled on top
29.	118	45	F		

CHILD	CHILD DATA: 45 – 48 months continued								
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS				
30.	200	45	F		Played with rubber stopper				
31.	120	46	F						
32.	122	45	F		Played with rubber stopper				
33.	124	46	F		Tried to pull off cap				
34.	126	46	F						
35.	128	47	F		Shook				
36.	130	45	F		Played with rubber stopper				
37.	132	46	F		Put in mouth				
38.	134	47	F		Played with rubber stopper				
39.	136	46	F						
40.	138	45	F		Pulled/ bit/shook				

CHILD	DATA: 4	9 – 51 m	onths		
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	140	49	M		Squeezed rubber stopper
2.	142	49	M		
3.	144	49	M		Pulled
4.	146	50	M		Pulled on top
5.	148	50	M		
6.	150	51	M		Squeezed rubber stopper
7.	152	50	M		Squeezed rubber stopper
8.	154	49	M		
9.	156	49	M		Shook bottle
10.	158	49	M		Played with rubber stopper
11.	160	49	M		Twisted top
12.	162	51	M		Played with rubber stopper
13.	164	50	M		
14.	166	50	M		Twisted and pulled on top
15.	168	50	F		
16.	170	49	F		Played with rubber stopper
17.	172	49	F		Twisted and pulled
18.	174	49	F		
19.	176	50	F		Played with top
20.	178	50	F		Bit on the rubber
21.	180	50	F		
22.	182	51	F		Pulled on top hard
23.	184	49	F		
24.	186	49	F		Shook/played
25.	188	50	F		Shook bottle
26.	190	50	F		
27.	192	50	F		Rolled bottle
28.	194	49	F		Shook bottle
29.	196	49	F		
30.	198	50	F		Bit on the rubber

# EVALUATION OF 120ML BOTTLE 22MM/400 CLOSURE REPORT FOR SENIOR EFFECTIVENESS

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

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

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

# **ADULT RESECURRING 100%**

SENIOR	SENIOR ADULT: 50 - 54 YEARS										
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	TIME TO OPEN					
1.	01	02	52	M	PASS	:06/:09					
2.	03	04	50	M	PASS	:11/:09					
3.	05	06	51	M	PASS	:12/:08					
4.	07	08	51	M	PASS	:10/:06					
5.	09	10	52	M	PASS	:10/:05					
6.	11	12	52	M	PASS	:07/:06					
7.	13	14	50	M	PASS	:08/:11					
8.	15	16	50	M	PASS	:09/:06					
9.	17	18	53	F	PASS	:08/:07					
10.	19	20	53	F	PASS	:07/:12					
11.	21	22	50	F	PASS	:10/:05					
12.	23	24	50	F	PASS	:11/:07					
13.	25	26	52	F	PASS	:05/:11					
14.	27	28	50	F	PASS	:08/:07					
15.	29	30	53	F	PASS	:05/:09					

SENIOR	SENIOR ADULT: 50 - 54 YEARS continued									
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	TIME TO OPEN				
16.	31	32	55	F	PASS	:06/:05				
17.	33	34	55	F	PASS	:04/:12				
18.	35	36	54	F	PASS	:15/:13				
19.	37	38	50	F	PASS	:12/:09				
20.	39	40	50	F	PASS	:12/:11				
21.	41	42	54	F	PASS	:07/:06				
22.	43	44	54	F	PASS	:09/:06				
23.	45	46	50	F	PASS	:07/:04				
24.	47	48	50	F	PASS	:08/:07				
25.	49	50	52	F	PASS	:13/:12				

SENIOR	ADULT:	55 - 59 YEA	ARS			
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	TIME TO OPEN
1.	51	52	58	M	PASS	:16/:15
2.	53	54	56	M	PASS	:06/:08
3.	55	56	57	M	PASS	:06/:05
4.	57	58	56	M	PASS	:13/:12
5.	59	60	55	M	PASS	:14/:09
6.	61	62	55	M	PASS	:15/:11
7.	63	64	55	M	PASS	:12/:08
8.	65	66	56	M	PASS	:09/:07
9.	67	68	56	F	PASS	:05/:04
10.	69	70	56	F	PASS	:08/:06
11.	71	72	55	F	PASS	:07/:06
12.	73	74	55	F	PASS	:05/:05
13.	75	76	56	F	PASS	:04/:04
14.	77	78	55	F	PASS	:10/:05
15.	79	80	57	F	PASS	:06/:04
16.	81	82	57	F	PASS	:08/:06
17.	83	84	55	F	PASS	:11/:07
18.	85	86	55	F	PASS	:08/:06
19.	87	88	56	F	PASS	:11/:06
20.	89	90	59	F	PASS	:08/:09
21.	91	92	58	F	PASS	:08/:06
22.	93	94	55	F	PASS	:08/:06
23.	95	96	56	F	PASS	:18/:14
24.	97	98	56	F	PASS	:08/:10
25.	99	100	57	F	PASS	:06/:05

SENIOR	ADULT:	60 - 70 YEA	ARS			
	PKG#	PKG#	AGE	GENDER	PASS/FAIL	TIME TO OPEN
1.	101	102	60	M	PASS	:11/:06
2.	103	104	61	M	PASS	:08/:09
3.	105	106	62	M	PASS	:08/:06
4.	107	108	60	M	PASS	:12/:07
5.	109	110	62	M	PASS	:09/:08
6.	111	112	63	M	PASS	:07/:05
7.	113	114	66	M	PASS	:12/:09
8.	115	116	68	M	PASS	:19/:16
9.	117	118	62	M	PASS	:17/:14
10.	119	120	60	M	PASS	:04/:07
11.	121	122	64	M	PASS	:05/:13
12.	123	124	63	M	PASS	:05/:04
13.	125	126	60	M	PASS	:08/:06
14.	127	128	63	M	PASS	:07/:06
15.	129	130	64	M	PASS	:10/:07
16.	131	132	64	F	PASS	:05/:04
17.	133	134	60	F	PASS	:05/:06
18.	135	136	65	F	PASS	:05/:05
19.	137	138	60	F	PASS	:12/:10
20.	139	140	61	F	PASS	:06/:04
21.	141	142	61	F	PASS	:06/:07
22.	143	144	66	F	PASS	:11/:09
23.	145	146	61	F	PASS	:05/:10
24.	147	148	66	F	PASS	:05/:06
25.	149	150	63	F	PASS	:05/:15
26.	151	152	64	F	PASS	:10/:11
27.	153	154	67	F	PASS	:22/:14
28.	155	156	68	F	PASS	:22/:06
29.	157	158	65	F	PASS	:05/:06
30.	159	160	70	F	PASS	:08/:06
31.	161	162	63	F	PASS	:07/:06
32.	163	164	64	F	PASS	:12/:14
33.	165	166	65	F	PASS	:04/:06
34.	167	168	60	F	PASS	:12/:12
35.	169	170	60	F	PASS	:06/:08
36.	171	172	62	F	PASS	:13/:13
37.	172	174	61	F	PASS	:11/:10
38.	175	176	60	F	PASS	:11/:09
39.	177	178	66	F	PASS	:15/:13
40.	179	180	67	F	PASS	:14/:10

SENIOR ADULT: 60 - 70 YEARS continued						
41.	181	182	68	F	PASS	:15/:15
42.	183	184	62	F	PASS	:14/:14
43.	185	186	60	F	PASS	:16/:14
44.	187	188	60	F	PASS	:14/:15
45.	189	190	61	F	PASS	:10/:09
46.	191	192	64	F	PASS	:06/:09
47.	193	194	60	F	PASS	:08/:11
48.	195	196	61	F	PASS	:12/:09
49.	197	198	60	F	PASS	:11/:12
50.	199	200	60	F	PASS	:10/:12

# GENERAL OBSERVATIONS: SENIORS

The seniors had little trouble opening and closing the bottle properly. The majority expressed knowing how to open the bottle without having to read the instructions.

### **CHILDREN**

The majority of children could not comprehend how to get the top off the bottle. However, they love shaking the bottle and turning it upside down. They were fascinated with squeezing the rubber top

### **Test Supervisors**

- Debbie Brooks
- Julie Ford
- Jeremy Brooks
- John Buckner
- Raechel Buckner