

**Evaluation of the
Glass Dropper Bottle
As a Poison Prevention Package for
Rock Bottom Bottles, LLC**

By

**BITNER ASSOCIATES, INC.
1001 FOREST TRAIL
SUGAR GROVE, ILLINOIS 60554**



design, development, and
commercialization of **effective** packaging

May 10, 2015

Rock Bottom Bottles, LLC
7909 Osprey Hammock Court
Sarasota, Fla 34240

Attention: James Cirillo;
Herein is our report titled **“Glass Dropper Bottle”** as a Poison Protection Package for Rock Bottom Bottles, LLC.

The **Glass Dropper Bottle** was evaluated using the Consumer Product Safety Commission Protocol and Standards. The study indicates the Glass Dropper Bottle/ Rubber Stopper fulfills the requirements for a Poison Prevention Package as per 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, appearing to read "John Bitner", written in a cursive style.

John Bitner
President

June 28, 2015

Rock Bottom Bottles, LLC
7909 Osprey Hammock Court
Sarasota, Fla 34240

To: Michael Boling <michael@rockbottombottles.com>
Subject: RE: is Rock Bottom Bottles compliant

Michael,

We are compliant with successful passage of CFR Title 16 Part 1700.20 which is the protocol mandated to be administered by CPSC.

The passing of CFR Title 16 Part 1700.20 permits you to certify that said package meets the “special” packaging effectiveness specifications. CFR Title 16 Part 1700.15 is not a protocol. It merely outlines the standards necessary for submission of that package for protocol administration.

CFR Title 16 Part 1700.15 presents the general standards necessary for a package to function with effectiveness specifications factors. It is not meant to evaluate or substitute for the appropriate scientific technical evaluations required to maintain child-resistant effectiveness over the life of the product. CFR Title 16 Part 1700.20 is not intended to measure those functional aspects which may lessen with time based on physical wear, stress factors, force required for activation, or compatibility of product. The intent of protocol 1700.20 is to solely substantiate seal integrity related to safety of child resistant/senior friendly effectiveness of the “special” packaging.

We fully support CFR Title 1700.15 where and when it is applicable to administration of CPSC protocol CFR Title 16 Part 1700.20.

Regards,
John



John Bitner
President



Gilla Operations, LLC
475 Fentress Blvd, Unit L
Daytona Beach, FL 32114

CERTIFICATE OF COMPLIANCE

Identification of the product covered by this certificate:

Name of Company: Gilla Operations, LLC

Name of Line: Coil Glaze, The Mad Alchemist, Craft Clouds, Craft Vapes, Vape Warriors, Miss Pennysworth Elixers, Replicant, Surf Sauce, Siren, The Drip Factory, Crown

Nicotine Levels: 0mg (0.0%), 3mg (0.3%), 6mg (0.6%), 12mg (1.2%), 18mg (1.8%)

Bottle Sizes: 10ml, 15ml, 30ml, 60ml, and 120ml

Citation to each CPSC product safety regulation to which this product is being certified:

16 CFR Title 16 Part 1700.20

Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:

Rock Bottom Bottles LLC
1447 Tallevast Road
Sarasota, FL 34243
See Attached GCC from Rock Bottom Bottles LLC

Contact information for the individual maintaining records of test results:

Nichole Southern
8412 Sabal Industrial Blvd. Suite B, Tampa, FL 33619
813.684.8273

Place where this product was manufactured:

XiyongXinhua
Hebei Povince, China

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

Testing conducted from 5-2-2015 – 5-9-2015
Chicago and south, west villages thereof

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

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

LABEL EXAMPLES





ROCKBOTTOMBOTTLES



ROCKBOTTOMBOTTLES

1447 Tallevast Road

Sarasota, FL 34243

Certificate of Compliance

1. **Identification of the product covered by this certificate:**
2. **Citation to each CPSC product safety regulation to which this product is being certified:**
16 CFR Title 16 Part 1700.20
3. **Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:**
Rock Bottom Bottles LLC
4. **Contact information for the individual maintaining records of test results:**
Michael Boling
941-444-5485
941-539-7878
5. **Place where this product was manufactured:**
XiyingXinhua
Hebei Povince, China
6. **Date and place where this product was tested for compliance with the regulation(s) cited:**
Testing conducted from 5-2-2015 – 5-9-2015
Chicago and south, west villages thereof
7. **Identification of any third-party facility on whose testing the certificate depends:**
Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL 60554

Consumer Product Safety Commission protocol CFR Title 16 Part 1700.20 administered by





ROCKBOTTOMBOTTLES



1447 Tallevast Road

Sarasota, FL 34243

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16 CFR Title 16 Part 1700.20
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Rock Bottom Bottles LLC
4. **Contact information for the individual maintaining records of test results:**
Michael Boling
941-444-5485
941-539-7878
5. **Place where this product was manufactured:**
XiyingXinhua
Hebei Povince, China
6. **Date and place where this product was tested for compliance with the regulation(s) cited:**
Testing conducted from 5-2-2015 – 5-9-2015
Chicago and south, west villages thereof
7. **Identification of any third-party facility on whose testing the certificate depends:**
Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL 60554

Consumer Product Safety Commission protocol CFR Title 16 Part 1700.20 administered by





ROCKBOTTOMBOTTLES



ROCKBOTTOMBOTTLES

1447 Tallevast Road

Sarasota, FL 34243

Certificate of Compliance

1. **Identification of the product covered by this certificate:**
 1. **Glass Dropper Bottle**
 2. **Bottle: GLASS 10ml-120ml Closure outer: POLYPROPYLENE Closure inner: POLYPROPYLENE**

2. **Citation to each CPSC product safety regulation to which this product is being certified:**
16 CFR Title 16 Part 1700.20
3. **Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:**
Rock Bottom Bottles LLC
4. **Contact information for the individual maintaining records of test results:**
Michael Boling
941-444-5485
941-539-7878
5. **Place where this product was manufactured:**
XiyongXinhua
Hebei Povince, China
6. **Date and place where this product was tested for compliance with the regulation(s) cited:**
Testing conducted from 5-2-2015 – 5-9-2015
Chicago and south, west villages thereof
7. **Identification of any third-party facility on whose testing the certificate depends:**
Bitner Associates, Inc.
1001 Forest Trail
Sugar Grove, IL 60554

Consumer Product Safety Commission protocol CFR Title 16 Part 1700.20 administered by





ROCKBOTTOMBOTTLES



1447 Tallevast Road

Sarasota, FL 34243

Certificate of Compliance

1. **Identification of the product covered by this certificate:**
 1. **Bottle: 10ml- 100ml Polyethylene terephthalate (PET) and (LDPE)**
 2. **Closure outer: Polypropylene (PP)**
 3. **Closure inner: Polypropylene (PP)**
2. **Citation to each CPSC product safety regulation to which this product is being certified:**

16 CFR Title 16 Part 1700.20
3. **Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:**

Rock Bottom Bottles LLC
4. **Contact information for the individual maintaining records of test results:**

Michael Boling
941-444-5485
941-539-7878
5. **Place where this product was manufactured:**

Luqua Sijiazhuang
Hebei Povince, China
6. **Date and place where this product was tested for compliance with the regulation(s) cited:**

Testing conducted from 09-12-2015 –10-3-2015
Chicago and south, west villages thereof
7. **Identification of any third-party facility on whose testing the certificate depends:**

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

Consumer Product Safety Commission protocol CFR Title 16 Part 1700.20 administered by



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I. SUMMARY

Report to: James Cirillo
ROCK BOTTOM BOTTLES, LLC

Date: May 9, 2015
Samples of: Glass Dropper Bottles

Contract No.: 1371-179
Samples Received: May 02, 2015
Submitted by: James Cirillo

Objective

Rock Bottom Bottles submitted the **Glass Dropper Bottle** for a study to determine if it is compliant 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 **Glass Dropper Bottle** meets the **standards for poison prevention packaging** according to current C.F.R. Title 16, Part 1700.20.

II. INTRODUCTION

Rock Bottom Bottles wished to determine if the **Glass Dropper Bottle** fulfills the Consumer Product Safety Commission's (CPSC) current standards and protocols 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 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+

(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 ∇ 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 ∇ $\frac{1}{2}$ ounce for the CT-type closure and 8 drams ∇ 4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

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

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

Test Instructions for Senior Test

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

1. No adult with a permanent or temporary illness, injury, or disability 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 packages were the Glass Dropper Bottle. For purposes of this protocol administration, all bottles were partially filled with water. Tamper Evident band was disengaged prior to protocol.. Directions to remove closure were _ 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 e-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: Glass Dropper Bottle



Glass Dropper Bottle_

Bottle: GLASS
Closure outer: POLYPROPYLENE
Closure inner: 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
- * 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 100% of the children failed to open the package before demonstration and 97% of the children failed to open a package following demonstration for a total of 97 successful child panelists. This represents a child-resistant effectiveness of **97%**

Senior Adult Use Effectiveness

Senior panel consisted of 69 females and 31 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.

Glass 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 **Glass 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 GLASS DROPPER BOTTLE AS A CHILD-RESISTANT PACKAGE FOR ROCK BOTTOM BOTTLES

Table 1. Package opening test 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	1	1
45-48	20	20	40	0	0	0	0	0
49-51	14	16	30	0	0	2	0	2
TOTAL	48	52	100	0	0	2	1	3

CHILD-RESISTANT EFFECTIVENESS = 97%

CHILD DATA: 42 – 44 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	197	43	M	N/A	Twisted cap
2.	200	43	M	N/A	Twisted cap
3.	172	42	M	N/A	
4.	111	42	M	N/A	
5.	190	44	M	N/A	
6.	182	44	M	N/A	
7.	156	44	M	N/A	Twisted cap
8.	176	44	M	N/A	Twisted cap
9.	187	44	M	N/A	
10.	198	42	M	N/A	
11.	160	42	M	N/A	
12.	170	42	M	N/A	
13.	185	42	M	N/A	
14.	196	42	M	N/A	Bit on rubber
15.	127	42	F	N/A	

CHILD DATA: 42 – 44 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
16.	184	43	F	N/A	Twisted cap
17.	132	44	F	N/A	Twisted cap
18.	134	44	F	N/A	
19.	130	43	F	N/A	Bit on rubber
20.	129	43	F	N/A	Chewed on rubber top
21.	114	42	F	N/A	
22.	139	42	F	N/A	
23.	125	43	F	N/A	
24.	169	44	F	N/A	
25.	141	42	F	N/A	Bit on rubber
26.	143	42	F	N/A	Shook and played with it
27.	157	43	F	N/A	Shook bottle
28.	155	44	F	N/A	Shook bottle
29.	178	43	F	N/A	Tisted cap
30.	166	42	F	N/A	Biting on rubber

CHILD DATA: 45 – 48 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	75	45	M	N/A	
2.	138	45	M	N/A	Has a pool in his yard
3.	80	45	M	N/A	
4.	125	46	M	N/A	
5.	117	47	M	N/A	Bit on rubber
6.	78	45	M	N/A	Placed stopper in mouth
7.	139	45	M	N/A	
8.	87	48	M	N/A	Talked the whole 10 min
9.	82	45	M	N/A	Fiddled with package
10.	11	47	M	N/A	
11.	64	48	M	N/A	
12.	53	46	M	N/A	Bit on rubber
13.	48	47	M	N/A	
14.	63	47	M	N/A	Shook bottle
15.	23	45	M	N/A	Shook bottle
16.	48	46	M	N/A	
17.	96	45	M	N/A	
18.	19	47	M	N/A	Picked at the rubber
19.	91	46	M	N/A	
20.	32	45	M	N/A	

CHILD DATA: 45 – 48 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
21.	36	45	F	N/A	Bit on rubber
22.	172	48	F	N/A	
23.	67	45	F	N/A	Shook bottle
24.	17	46	F	N/A	Twisted and talked
25.	122	45	F	N/A	Bit on rubber
26.	84	46	F	N/A	
27.	80	47	F	N/A	
28.	110	45	F	N/A	
29.	112	45	F	N/A	Shook bottle
30.	81	48	F	N/A	Shook bottle
31.	167	45	F	N/A	Shook bottle
32.	193	46	F	N/A	
33.	120	46	F	N/A	
34.	119	46	F	N/A	Bit on rubber
35.	99	45	F	N/A	
36.	201	46	F	N/A	Shook liquid
37.	134	45	F	N/A	Bit on rubber
38.	175	45	F	N/A	Played with bottle
39.	144	47	F	N/A	
40.	159	47	F	N/A	Shook bottle

CHILD DATA: 49 – 51 months					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
1.	114	51	M	N/A	Shook bottle
2.	74	49	M	N/A	
3.	124	50	M	N/A	
4.	10	50	M	7:52	Bit on rubber
5.	24	49	M	N/A	
6.	02	50	M	N/A	Shook bottle
7.	12	50	M	N/A	Twisted and shook
8.	41	50	M	N/A	
9.	7	51	M	N/A	
10.	69	49	M	8:16	Twisted and pulled
11.	58	49	M	N/A	Twisted cap
12.	43	49	M	N/A	Shook bottle
13.	66	51	M	N/A	
14.	46	51	M	6:43	Twisted and pulled
15.	35	51	F	N/A	

CHILD DATA: 49 – 51 months continued					
	PKG#	AGE	GENDER	TIME to OPEN	COMMENTS
16.	05	51	F	N/A	
17.	64	51	F	N/A	Bit on rubber
18.	04	51	F	N/A	
19.	56	51	F	N/A	Shook bottle
20.	18	51	F	N/A	Twisted cap over and over
21.	44	51	F	5:54	Twisted and pulled
22.	52	50	F	N/A	
23.	39	51	F	N/A	
24.	96	50	F	N/A	
25.	88	51	F	N/A	Bit on rubber
26.	127	50	F	N/A	
27.	98	50	F	N/A	Shook bottle
28.	130	49	F	N/A	Shook bottle
29.	137	49	F	N/A	
30.	120	51	F	N/A	

EVALUATION OF THE GLASS DROPPER BOTTLE REPORT FOR SENIOR EFFECTIVENESS FOR ROCK BOTTOM BOTTLES

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

	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#		AGE	GENDER	PASS/FAIL	COMMENTS
1.	191	193	51	F	PASS	:24/:08
2.	159	196	53	F	PASS	:33/:23
3.	192	134	54	F	PASS	:38/:22
4.	191	200	52	F	PASS	:20/:18
5.	150	170	50	F	PASS	:54/:11
6.	183	160	53	F	PASS	:10/:14
7.	141	156	54	F	PASS	:28/:16
8.	35	52	52	F	PASS	:26/:21
9.	30	64	54	F	PASS	:19/:18
10.	29	11	54	F	PASS	:22/:20
11.	08	58	54	F	PASS	:19/:16
12.	12	63	53	F	PASS	:14/:13
13.	37	69	52	F	PASS	:17/:12
14.	01	56	52	F	PASS	:11/:11
15.	31	03	54	F	PASS	:33/:25
16.	17	66	53	F	PASS	:19/:16
17.	32	48	52	F	PASS	:19/:18
18.	61	10	52	M	PASS	:25/:23
19.	112	142	54	M	PASS	:39/:33
20.	20	27	53	M	PASS	:25/:19
21.	45	64	52	M	PASS	:26/:24
22.	09	05	54	M	PASS	:21/:22
23.	34	39	50	M	PASS	:23/:12
24.	50	35	52	M	PASS	:48/:34
25.	22	46	53	M	PASS	:22/:17

SENIOR ADULT: 55 – 59 YEARS						
	PKG#		AGE	GENDER	PASS/FAIL	COMMENTS
1.	47	36	55	F	PASS	:37/:20
2.	155	167	55	F	PASS	:16/:05
3.	164	144	55	F	PASS	:37/:15
4.	146	111	55	F	PASS	:30/:30
5.	143	176	55	F	PASS	:41/:21
6.	13	04	55	F	PASS	:24/:11
7.	26	12	55	F	PASS	:21/:32
8.	19	53	55	F	PASS	:19/:15
9.	68	23	56	F	PASS	:27/:20
10.	89	117	56	F	PASS	:19/:18
11.	126	120	58	F	PASS	:20/:14
12.	116	123	55	F	PASS	:25/:23

SENIOR ADULT: 55 – 59 YEARS continued						
	PKG#		AGE	GENDER	PASS/FAIL	COMMENTS
13.	137	138	59	F	PASS	:20/:17
14.	126	127	58	F	PASS	:21/:17
15.	140	138	56	F	PASS	:22/:22
16.	104	83	55	F	PASS	:23/:26
17.	115	19	57	F	PASS	:24/:20
18.	121	134	56	M	PASS	:23/:22
19.	42	43	55	M	PASS	:47/:58
20.	57	62	58	M	PASS	:13/:10
21.	52	07	56	M	PASS	:32/:23
22.	38	55	59	M	PASS	:29/:15
23.	161	19\	57	M	PASS	:39/:13
24.	173	190	59	M	PASS	:49/:32
25.	129	172	59	M	PASS	:56/:48

SENIOR ADULT: 60 - 70 YEARS						
	PKG#		AGE	GENDER	PASS/FAIL	COMMENTS
1.	180	185	66	F	PASS	:39/:25
2.	148	159	69	F	PASS	:37/:16
3.	158	175	61	F	PASS	:15/:14
4.	181	182	67	F	PASS	:51/:10
5.	174	198	69	F	PASS	:45/:25
6.	16	18	60	F	PASS	:14/:14
7.	40	172	63	F	PASS	:22/:14
8.	106	111	63	F	PASS	:20/:12
9.	91	112	63	F	PASS	:18/:12
10.	102	78	63	F	PASS	:16/:12
11.	131	139	63	F	PASS	:22/:12
12.	109	110	64	F	PASS	:20/:18
13.	107	88	65	F	PASS	:22/:14
14.	90	74	65	F	PASS	:20/:17
15.	92	114	66	F	PASS	:20/:16
16.	76	23	66	F	PASS	:20/:12
17.	72	118	67	F	PASS	:16/:14
18.	91	94	64	F	PASS	:20/:11
19.	100	80	64	F	PASS	:25/:18
20.	85	119	65	F	PASS	:25/:17
21.	77	90	67	F	PASS	:24/:27
22.	103	75	60	F	PASS	:20/:15
23.	84	105	61	F	PASS	:23/:18
24.	74	73	62	F	PASS	:19/:12

SENIOR ADULT: 60 - 70 YEARS continued						
	PKG#		AGE	GENDER	PASS/FAIL	COMMENTS
25.	83	90	68	F	PASS	:19/:18
26.	78	122	69	F	PASS	:17/:14
27.	115	114	62	F	PASS	:22/:18
28.	140	141	66	F	PASS	:36/:22
29.	163	169	68	F	PASS	:48/:22
30.	124	125	69	F	PASS	:22/:18
31.	188	194	66	F	PASS	:18/:22
32.	147	162	70	F	PASS	:36/:25
33.	153	155	66	F	PASS	:23/:36
34.	156	157	60	F	PASS	:22/:18
35.	142	143	65	F	PASS	:22/:17
36.	25	02	65	M	PASS	:36/:27
37.	60	24	65	M	PASS	:36/:27
38.	59	67	67	M	PASS	:23/:18
39.	49	17	67	M	PASS	:18/:19
40.	57	41	61	M	PASS	:20/:20
41.	70	44	65	M	PASS	:26/:19
42.	160	187	60	M	PASS	:23/:17
43.	133	94	60	M	PASS	:19/:15
44.	18	96	60	M	PASS	:21/:16
45.	129	130	63	M	PASS	:17/:15
46.	124	125	60	M	PASS	:20/:15
47.	128	132	66	M	PASS	:28/:24
48.	71	18	68	M	PASS	:19/:13
49.	108	162	60	M	PASS	:22/:14
50.	137	139	62	M	PASS	:18/:14

GENERAL OBSERVATIONS:

SENIORS

The seniors had trouble reading the directions on the closure. They had little trouble opening the bottle, some struggled with re-securing.

CHILDREN

All of the 100 children repeatedly twisted the cap over and over. The children like to shake bottles that contain a liquid, these children were no exception. They passed some amount of time chewing and biting on the rubber stopper. The three that did get into the package were twisting while pulling very hard “using all their muscles” as one little guy stated.

Test Supervisors

- Jennifer Burton
- Jeremy Brooks
- Debra Bitner
- Julie Ford
- Jamie Radkowski