

May 19, 2016

Dear Valued Customer:

Subject:

Child-Resistant Closure Protocol Test Results for:

28mm/400 Ultra Loc – Full Adult (Age 50-70) with child resecuring, Children

38mm/400 Ultra Loc – Full Adult (Age 50-70) with child resecuring, Senior Adult (60-70) with child resecuring; Children

Enclosed with this letter is a copy of the results of the protocol test conducted with adults and children on child-resistant closures produced by Berry Plastics.

It is important to note that on the protocol test results we are sending to you we have recorded the container type and size, the closure components including the liner, the package preparation conditions, as well as the test conditions. The closures, lining materials, and containers selected by Berry for protocol testing are not intended to duplicate any specific customer packages or specifications.

The performance of child-resistant closures is dependent upon the torque retained by these closures after their application to a specific package. In order to obtain proper torque values, it is most important for the packager to perform torque degradation studies and follow the package preparation precautions and capping procedures detailed in Berry Procedure Manual for the application of two-piece child-resistant closures. Copies of this Procedure Manual can be obtained through your Berry Plastics sales representative.

It is particularly important that you, as the packager using child-resistant packaging, carefully monitor the performance of your production line and the performance of your package in the marketplace since both the Poison Prevention Packaging Act as administered by the Consumer Product Safety Commission and the Federal Insecticide, Fungicide, and Rodenticide Act as administered by the Environmental Protection Agency place the responsibility for proper performance of special packaging on the packager.

Further significance of these protocol test results lies in the fact that they in no way imply CR closures will perform under all conditions of application, package storage and package handling or will perform satisfactorily on containers of a different size and shape. These studies do document that the Berry closure has the capability to fulfill the children requirements as per the current Code of Federal Regulations (CFR) Title 16, Part 1700.

Lastly, whether you accept the Berry protocol data or elect to generate protocol data on your own specific packages can only be determined after you have considered <u>all</u> the requirements for child-resistant packaging, as detailed in the regulation applicable to your particular product and have discussed this entire matter with your legal counsel.

We certainly hope the enclosed information will be helpful to you. If you have any questions concerning it, we would be pleased to discuss them with you.

Kristi J. Ritter

Kusti J Pitter

Regulatory Affairs Specialist



# \* \* \* ADULT PROTOCOL TEST with child resecuring \* \* \*

AGE GROUP: 50-70 YEARS

Test Number:

REX14-01A

**Test Date:** 

February 25 - March 13, 2014

CAP INFORMATION

CONTAINER INFORMATION

Closure type:

Ultra Loc

Bottle

Size:

28mm

Size:

30cc

Inner Material:

Polypropylene

Finish:

28/400

**Outer Material:** 

Polypropylene

Shape:

Round

Liner:

35WLP/SG 75M

Container Material:

Container Type:

**HDPE** 

Agency:

Start date: February 27, 2014

End date: March 18, 2014

### PACKAGE PREPARATION

Initial Application Torque: 17.0 torque inch pounds

### TEST RESULTS

NO. TESTED SEX

NO.

SUCCESSFULLY **OPENED AND** RECLOSED

**FEMALE** 

70

70

MALE

30

30

**TOTAL** 

PERCENT

97

# AGE GROUP **PROPORTION OPENED & RECLOSED**

<u>50-59</u>	<u>60-70</u>	<b>Initial SAUE</b>	<b>Child Portion Opened</b>	Final SAUE
1.00	1.00	1.00	0.05	1.00





# \* \* \* CHILDREN'S PROTOCOL TEST \* \* \*

**Test Number:** 

REX14-01

**Test Date:** 

February 25 - March 13, 2014

CAP INFORMATION

CONTAINER INFORMATION

Closure type:

Ultra Loc

Container Type:

Bottle

Size:

28mm

Size:

30cc

**Inner Material:** 

Polypropylene

Finish:

28/400

**Outer Material:** 

Polypropylene

Shape:

Round

Liner:

Container Material:

**HDPE** 

35WLP/SG 75M

Agency:

Start date: February 25, 2014

End date: March 13, 2014

# PREPARATION OF THE TEST PACKAGES

Initial application:

17 torque inch-lbs

Re-application:

12 torque inch-lbs

### TEST RESULTS

### NUMBER OPENED

AGE (MO.)	NO. CHILDREN TESTED	GIRLS	BOYS	5 MIN. BEFORE DEMONSTRATION	5 MIN. AFTER DEMONSTRATION
42	3	1	2	0	0
43	5	3	2	0	0
44	7	3	4	0	0
45	5	3	2	0	0
46	9	5	4	0	0
47	4	1	3	0	1
48	2	1	1	0	0
49	3	1	2	0	0
50	6	4	2	0	0
51	6	3	3	0	0
TOTALS:	50	25	25	0	1

Summary - 100% Effectiveness before demonstration; 98% Effectiveness after demonstration





# \* \* \* ADULT PROTOCOL TEST \* \* \*

AGE GROUP: 50-70 YEARS

Test Number: N/A

**Test Date:** 

March 2004 - May 2004

**CLOSURE INFORMATION** 

CONTAINER INFORMATION

Closure type:

Ultra Loc

Container Type:

Bottle

Size:

38mm

Size:

120cc

Inner Material:

Polypropylene

Finish:

38/400

Outer Material:

Polypropylene

Shape:

Round

Liner:

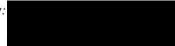
Not listed in report

Container Material:

**HDPE** 

100

Agency:



Start Date: March 18, 2004

End Date: May 5, 2004

#### PACKAGE PREPARATION

Initial Application Torque: 21.0 torque inch pounds

### **TEST RESULTS**

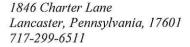
SEX	NO. TESTED	NO. SUCCESSFULLY OPENED AND RECLOSED
FEMALE	70	70
MALE	30	30
TOTAL		

PERCENT

AGE GROUP PROPORTION OPENED & RECLOSED

<u>50-59</u>	<u>60-70</u>	<b>Initial SAUE</b>	<b>Child Portion Opened</b>	Final SAUE
1.00	1.00	1.00	0.010	1.00







# \* \* \* SENIOR- ADULT PROTOCOL TEST \* \* \*

AGE GROUP: 60-70 YEARS

Test Number: REX12-35A

**Test Date:** 

May 2012

**CLOSURE INFORMATION** 

CONTAINER INFORMATION

Closure Type: Ultra Loc

Container Type:

**Bottle** 

Size:

38mm

Size:

100cc

Inner Material:

Polypropylene

Finish:

38-400

Outer material:

Polypropylene

Shape:

Round

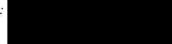
Liner:

40 F-217

Container Material:

**HDPE** 

Agency:



Start date: May 1, 2012

end date: May 3, 2012

### PACKAGE PREPARATION

Initial Application Torque: 12.0 torque inch-lbs

## **TEST RESULTS**

SEX	NO. TESTED	NO. SUCCESSFULLY OPENED AND RECLOSED
FEMALE	35	35
MALE	15	15
TOTAL	50	50
	PERCENT	100

**Initial SAUE Child Portion Opened Final SAUE** 100.0% 0.001 100.0%





# \* \* \* CHILDREN'S PROTOCOL TEST \* \* \*

**Test Number:** 

REX08-11

Test Date:

October 2008

CAP INFORMATION

CONTAINER INFORMATION

Closure type:

Ultra Loc

Container Type:

Bottle

Size:

38mm

Size:

120cc

Inner Material:

Polypropylene

Finish:

38/400

Outer Material:

Polypropylene

Shape:

Round

Liner:

Not listed in report

**Container Material:** 

**HDPE** 

Agency:

Start date: October 14, 2008

End date: October 17, 2008

# PREPARATION OF THE TEST PACKAGES

Initial application:

21 torque inch-lbs

Re-application:

21 torque inch-lbs

### TEST RESULTS

### **NUMBER OPENED**

AGE (MO.)	NO. CHILDREN TESTED	GIRLS	BOYS	5 MIN. BEFORE DEMONSTRATION	5 MIN. AFTER DEMONSTRATION
42	7	3	4	0	0
43	4	2	2	0	0
44	4	2	2	0	0
45	7	4	3	0	0
46	4	2	2	0	0
47	2	1	1	0	0
48	7	3	4	0	0
49	11	6	5	0	0
50	2	1	1	0	0
51	2	1	1	0	0
TOTALS:	50	25	25	0	0

Summary - 100% Effectiveness before demonstration; 100% Effectiveness after demonstration

