

Dear Valued Customer,

Subject:

Child-Resistant Closure Protocol Test Results for:

VCCRBK20

-Full Adult (Age 50-70),

-Senior Adult (60-70)

-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 Global.

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 Global 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 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.

Kusti J Pitter

Kristi J. Ritter

Regulatory Affairs Specialist



1846 Charter Lane Lancaster, Pennsylvania, 17601 717-390-8449

* * * SENIOR ADULT PROTOCOL TEST * * *

AGE GROUP: 50-70 YEARS

Test Number: REX12-22A

Test Date:

March-May 2012

CLOSURE INFORMATION

CONTAINER INFORMATION

Closure Type: Purse-Pak Closure

Container Type:

VCCRBK20

Size:

20mm

Size:

20mm

Inner Material:

LLDPE fitment

Finish:

20mm/400

Outer material:

Polypropylene

Shape:

Round

Liner:

None

Container Material:

Polypropylene

PACKAGE PREPARATION

Initial Application Torque: Presented to adult in

locked position

1 Week Removal Torque (avg.): n/a

End of Test Removal Torque (avg.): n/a

TEST RESULTS

SEX	NO. TESTED	NO. SUCCESSFULLY OPENED AND RECLOSED
FEMALE	70	63
MALE	30	29
TOTAL PACKAGES TOTAL PERCENT	100 100%	92 92%

PROTOCOL SUMMARY:

Initial SAUE%

Child Portion Opened%

Final SAUE%

n/a

n/a

92%

Based on test results, the submitted package meets the senior-adult criteria set forth by 16 CFR Part 1700.15 and 1700.20.



Telephone (717) 299-6511 * Fax (717) 299-5844

Test Number: 17-011

Date: 08/22/2018

* * * Senior Adult (60-70) Protocol Test * * *

CLOSURE INFORMATION		CONTAINER INFORMATION		
Type: Size: Inner Material:	VCCRBK20 20mm	Type: Size: Finish:	Vial 20/400	
Outer Material: Liner:	Polypropylene fitment	Shape:	Cylinder Polypropylene	
Color:	white			

6 Year Requalification

Test Started:

12/06/2017

Test Completed:

12/17/2017

Comments: 5 adult failures to open (3 - 1st package; 2 - 2nd package)

TEST RESULTS

Sex	Nbr Tested	Nbr Successfully Opened and Reclosed
Female:	35	30
Male:	15	15
Total:	50	45
	Percent:	90.0

60-70	Initial SAUE	Not Re-Secured By	AdultsChild Portion Opened	Final SAUE
0.900	0.900	0.100	0.000	0.900

Test conducted complies with 16 CFR Part 1700.15 and 1700.20



Telephone (717) 299-6511 * Fax (717) 299-5844

Test Number: 17-012

Date: 08/22/2018

* * * Child Protocol Test * * *

C	LOSURE INFORMATION		CONTAINER INFORMATION
Type: Size: Inner Material:	VCCRBK20 20mm	Type: Size:	Vial
Outer Material: Liner: Color:	Polypropylene CY20SNOSSFT LLDPE fitment white	Finish: Shape: Material:	20/400 Cylinder Polypropylene

6 Year Requalification

Test Started:

11/16/2017

Test Completed:

01/18/2018

Comments: 5 child openings - all before demo; cycled 25x

TEST RESULTS					
				Nbr Opened	
Age (Months)	Nbr Tested	Girls	Boys	5 Min Before Demonstration	5 Min After Demonstration
42	8	.4	4	0	0
43	7	2	5	0	0
44	15	9	6	2	0
45	14	6	8	1	0
46	7	3	4	0	0
47	13	8	5	0	0
48	6	3	3	1	0
49	10	5	5	1	0
50	11	5	6	0	0
51	9	5	4	0	0
Totals:	100	50	50	5	0

Test conducted complies with 16 CFR Part 1700.15 and 1700.20