

GREAT LAKES MARKETING

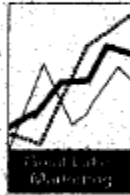
PREPARED FOR:

GUNN & RICHARDS

Child Panel
Secure Vials with Child-Resistant Caps
GLM 11180

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Child Panel

Introduction

Great Lakes Marketing conducted a test of the Secure Vials with Child-Resistant Caps using a panel of 50 children. The test protocol followed that written in the Federal Register, Title 16, Part 1700.20.

Summary of Test Results

Package Preparations: GLM personnel prepared the packages. The bottles were partially filled with beans and the closures were hand applied. The closures are not torque dependent. The testing protocol is in Appendix One.

Panel: 25 Females
 25 Males
 50 Total Panel

Number of Openings: 0 Openings before the demonstration
 1 Opening after the demonstration
 1 Total Opening

Test Results: First 5 Minutes: 100% Effectiveness
 Full 10 Minutes: 98.0% Effectiveness
 See Table One for interpretation.

Table One

Cumulative Number of Children	Before the Demonstration First 5 Minutes			After the Demonstration Full 10 Minutes		
	Pass	Continue	Fail	Pass	Continue	Fail
50	100% - 94%	92% - 80%	≤ 78%	100% - 90%	88% - 72%	≤ 70%
100	96% - 90%	89% - 82%	≤ 81%	94% - 85%	84% - 76%	≤ 75%
150	92.7% - 88%	87.3% - 83.3%	≤ 82.7%	89.3% - 83.3%	82.7% - 77.3%	≤ 76.7%
200	90.5% - 85%	--	≤ 84.5%	87% - 80%	--	≤ 79.5%

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RESULTS: Seconds to Open

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>OPENED AFTER DEMO</u>	1 2.0%	0 0.0%	0 0.0%	1 6.7%	1 4.0%	0 0.0%	0 0.0%	1 100.0%
<u>451-480 Seconds</u>	1 2.0%	0 0.0%	0 0.0%	1 6.7%	1 4.0%	0 0.0%	0 0.0%	1 100.0%
<u>Did not Open</u>	49 98.0%	15 100.0%	20 100.0%	14 93.3%	24 96.0%	25 100.0%	49 100.0%	0 0.0%

RESULTS: Method to open (For those who opened the package)

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	1	0	0	1	1	0	0	1
<u>Opened with Teeth</u>	1 100.0%	0 0.0%	0 0.0%	1 100.0%	1 100.0%	0 0.0%	0 0.0%	1 100.0%

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PANEL: Age of Child (in months)

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>42-44 Months</u>	15 30.0%	15 100.0%	0 0.0%	0 0.0%	7 28.0%	8 32.0%	15 30.6%	0 0.0%
<u>45-48 Months</u>	20 40.0%	0 0.0%	20 100.0%	0 0.0%	10 40.0%	10 40.0%	20 40.8%	0 0.0%
<u>49-51 Months</u>	15 30.0%	0 0.0%	0 0.0%	15 100.0%	8 32.0%	7 28.0%	14 28.6%	1 100.0%

PANEL: Closure testing experience of child (NOTE: No child was tested before with a similar package)

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>Has Been Tested Before, Different Day</u>	28 56.0%	6 40.0%	12 60.0%	10 66.7%	12 48.0%	16 64.0%	27 55.1%	1 100.0%
<u>First Package Ever Tested</u>	16 32.0%	9 60.0%	5 25.0%	2 13.3%	10 40.0%	6 24.0%	16 32.7%	0 0.0%
<u>Second Package Tested on Same Day</u>	6 12.0%	0 0.0%	3 15.0%	3 20.0%	3 12.0%	3 12.0%	6 12.2%	0 0.0%

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PANEL: Tester Name (No tester should test more than 30% of the children)

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>G. Ford (21)</u>	14 28.0%	4 26.7%	5 25.0%	5 33.3%	6 24.0%	8 32.0%	14 28.6%	0 0.0%
<u>K. Berns (83)</u>	12 24.0%	5 33.3%	3 15.0%	4 26.7%	6 24.0%	6 24.0%	12 24.5%	0 0.0%
<u>K. Pankow (90)</u>	12 24.0%	3 20.0%	4 20.0%	5 33.3%	8 32.0%	4 16.0%	11 22.4%	1 100.0%
<u>J. Hepler (91)</u>	4 8.0%	2 13.3%	1 5.0%	1 6.7%	1 4.0%	3 12.0%	4 8.2%	0 0.0%
<u>J. Sebring (31)</u>	2 4.0%	0 0.0%	2 10.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
<u>L. Dvorak (66)</u>	2 4.0%	0 0.0%	2 10.0%	0 0.0%	2 8.0%	0 0.0%	2 4.1%	0 0.0%
<u>L. Steele (74)</u>	2 4.0%	1 6.7%	1 5.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
<u>R. Lamb (78)</u>	2 4.0%	0 0.0%	2 10.0%	0 0.0%	0 0.0%	2 8.0%	2 4.1%	0 0.0%

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OBSERVATIONS: Statement made: "You can use your teeth if you want to."

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>Yes</u>	46 92.0%	14 93.3%	19 95.0%	13 86.7%	22 88.0%	24 96.0%	45 91.8%	1 100.0%
<u>No</u>	4 8.0%	1 6.7%	1 5.0%	2 13.3%	3 12.0%	1 4.0%	4 8.2%	0 0.0%

OBSERVATIONS: Used teeth during the first five minutes of the test

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>Yes</u>	5 10.0%	1 6.7%	2 10.0%	2 13.3%	4 16.0%	1 4.0%	5 10.2%	0 0.0%
<u>No</u>	45 90.0%	14 93.3%	18 90.0%	13 86.7%	21 84.0%	24 96.0%	44 89.8%	1 100.0%

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OBSERVATIONS: Used teeth during the second five minutes of the test

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>Yes</u>	31 62.0%	8 53.3%	14 70.0%	9 60.0%	17 68.0%	14 56.0%	30 61.2%	1 100.0%
<u>No</u>	19 38.0%	7 46.7%	6 30.0%	6 40.0%	8 32.0%	11 44.0%	19 38.8%	0 0.0%

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OBSERVATIONS: 60 seconds prompt (if no action was taken by the child during the first 60 seconds of the test, the tester prompted the child to try)

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>No</u>	50 100.0%	15 100.0%	20 100.0%	15 100.0%	25 100.0%	25 100.0%	49 100.0%	1 100.0%

OBSERVATIONS: First 5 minutes total number of prompts

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>1 Prompt</u>	2 4.0%	1 6.7%	1 5.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
<u>2 Prompts</u>	1 2.0%	1 6.7%	0 0.0%	0 0.0%	0 0.0%	1 4.0%	1 2.0%	0 0.0%
<u>3 Prompts</u>	1 2.0%	0 0.0%	0 0.0%	1 6.7%	0 0.0%	1 4.0%	1 2.0%	0 0.0%
<u>No Prompts</u>	46 92.0%	13 86.7%	19 95.0%	14 93.3%	24 96.0%	22 88.0%	45 91.8%	1 100.0%

Child Panel

OBSERVATIONS: Second 5 minutes total number of prompts

	Total	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS	
		42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
<u>1 Prompt</u>	3 6.0%	1 6.7%	1 5.0%	1 6.7%	1 4.0%	2 8.0%	3 6.1%	0 0.0%
<u>2 Prompts</u>	7 14.0%	4 26.7%	2 10.0%	1 6.7%	3 12.0%	4 16.0%	7 14.3%	0 0.0%
<u>No Prompts</u>	40 80.0%	10 66.7%	17 85.0%	13 86.7%	21 84.0%	19 76.0%	39 79.6%	1 100.0%

PANEL: Test Site (Exact test site on file with Great Lakes Marketing)

	AGE OF CHILD (in months)			GENDER OF CHILD		TEST RESULTS		
	Total	42-44	45-48	49-51	Male	Female	Pass	Fail
	50	15	20	15	25	25	49	1
22	2 4.0%	1 6.7%	1 5.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
73	8 16.0%	0 0.0%	1 5.0%	7 46.7%	2 8.0%	6 24.0%	8 16.3%	0 0.0%
742	2 4.0%	1 6.7%	1 5.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
745	4 8.0%	2 13.3%	1 5.0%	1 6.7%	2 8.0%	2 8.0%	4 8.2%	0 0.0%
818	4 8.0%	0 0.0%	4 20.0%	0 0.0%	2 8.0%	2 8.0%	4 8.2%	0 0.0%
1038	2 4.0%	0 0.0%	2 10.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
1056	2 4.0%	2 13.3%	0 0.0%	0 0.0%	0 0.0%	2 8.0%	2 4.1%	0 0.0%
1365	2 4.0%	1 6.7%	1 5.0%	0 0.0%	1 4.0%	1 4.0%	2 4.1%	0 0.0%
3351	2 4.0%	1 6.7%	1 5.0%	0 0.0%	2 8.0%	0 0.0%	2 4.1%	0 0.0%
3445	2 4.0%	2 13.3%	0 0.0%	0 0.0%	2 8.0%	0 0.0%	2 4.1%	0 0.0%
7219	10 20.0%	3 20.0%	3 15.0%	4 26.7%	6 24.0%	4 16.0%	9 18.4%	1 100.0%
7220	2 4.0%	2 13.3%	0 0.0%	0 0.0%	2 8.0%	0 0.0%	2 4.1%	0 0.0%
7221	8 16.0%	0 0.0%	5 25.0%	3 20.0%	3 12.0%	5 20.0%	8 16.3%	0 0.0%

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Appendix One

Child Panel Test Protocol

- GLM personnel prepared the packages. The bottles were partially filled with beans and the closures were hand applied. The closures are not torque dependent. The packages containing the placebos were immediately accessible to the children and were not housed in any additional shelf packaging.
- All packages were handled so that no damage or jarring would occur during storage or transportation. The packages were not exposed to extreme conditions of heat or cold. The packages were tested at room temperature.
- The children had 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 was included in the test.
- The testing took place in a well-lighted location that was familiar to the children and that was isolated from all distractions.
- The tester, or another adult, escorted a pair of children to the test area. The tester placed the two so that there was no visual barrier between the children and the tester.
- The tester talked to the children to make them feel at ease.
- The children were not given the impression that they were in a race or contest. They were not told that the test was a game or that it was fun. They were not offered a reward.
- The tester recorded all data prior to, or after, the test so that full attention could be on the children during the test period.
- The tester used a stopwatch to record the number of seconds it took the child to open the package and to time the five-minute test periods.
- To begin the test, the tester handed each child an identical package and said, "PLEASE TRY TO OPEN THIS FOR ME."

(Continued)

- If a child refused to participate after the test had started, the tester reassured the child and gently encouraged the child to try. If the child continued to refuse, the tester asked the child to hold the package in his/her lap until the other child was finished. This pair of children was not eliminated from the results unless the refusing child disrupted the participation of the other child.
- Each child was given up to five minutes to open his/her package. The tester watched the children at all times during the test. The tester minimized conversation with the children as long as they continued to attempt to open their packages. The tester did not discourage the children verbally or with facial expressions. If a child got frustrated or bored and stopped trying to open his/her package, the tester reassured the child and gently encouraged the child to keep trying.
- The children were allowed freedom of movement to work on their packages as long as the tester was able to watch both children (e.g., they could stand up, bang or pry the package).
- If a child was endangering himself or others at any time, the test was stopped and the pair of children eliminated from the final results.
- The children were allowed to talk to each other about opening the packages and were allowed to watch each other try to open the packages.
- A child was not allowed to try to open the other child's package.
- If a child opened his/her package, the tester said, "THANK YOU," took the package from the child and put it out of the child's reach. The child was not asked to open the package a second time. The child was asked to stay until the other child finished.
- At the end of the five-minute period, the tester demonstrated how to open the package if either child had not opened his or her package. A separate "demo" package, identical to the child's package, was used for the demonstration.
- Prior to beginning the demonstration, the tester asked the children to hold their packages still or set the packages aside. The children were not allowed to continue to try to open their packages during the demonstration period.

- The tester said, "WATCH ME OPEN MY PACKAGE."
- Once the tester secured the children's full attention, he/she held the demo package approximately two feet from the children and opened the package at a normal speed as if he/she were going to be using the contents. There were no exaggerated opening movements.
- The tester did not discuss or describe how to open the package.
- To begin the second five-minute period, the tester said, "NOW YOU TRY TO OPEN YOUR PACKAGE."
- If one or both children had not used their teeth to try to open their packages during the first five minutes, the tester said immediately before beginning the second five-minute period, "YOU CAN USE YOUR TEETH IF YOU WANT TO." This was the only statement that the tester made about using teeth.
- The test continued for an additional five minutes or until both children had opened their packages, whichever came first.
- At the end of the test period, the tester said, "THANK YOU FOR HELPING." If children were told to use their teeth, the tester said, "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 said, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."
- The children were escorted back to their classroom, or other supervised area, by the tester or another adult.

Calculation of Child's Age in Months

1. Subtract the birth date from the test date.
2. Multiply the years by 12 to get months.
3. Add the months.
4. Add 1 month if the number of days is greater than 15.
5. Subtract 1 month if the number of days is less than -15 (e.g., -16, -17 etc.).
6. If the days are between -15 and +15, do not add or subtract a month (e.g., -15, -14, ..., +14, +15).

EXAMPLES

	Month	Day	Year
Test Date	8	26	2011
Birth Date	6	3	2007
	2	23	4

$$4 \times 12 = 48 + 2 = 50 + 1 = 51 \text{ months old.}$$

	Month	Day	Year
Test Date	8	3	2011
Birth Date	6	23	2007
	2	-20	4

$$4 \times 12 = 48 + 2 = 50 - 1 = 49 \text{ months old.}$$

	Month	Day	Year
Test Date	6	26	2011
Birth Date	8	11	2007
	-2	15	4

$$4 \times 12 = 48 + (-2) = 46 \text{ months old.}$$