Is Unit Dose Packaging Inherently Child-Resistant?

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ABSTRACT

In the United States, the regulations of the Poison Prevention Packaging Act (PPPA) require child-resistant packaging of 25 different "substances" including oral prescription drugs, ethylene glycol, methanol, sulfuric acid, aspirin, and acetaminophen. Any package that contains a substance regulated uner the PPPA must meet the child-resistant standards regardless of the package type. This means that 80 percent of children must NOT be able to access the packages within a specified time period. This standard applies to nonreclosable packaging such as unit dose blisters or pouches if they contain a regulated substance. Child-resistance of unit packaging is defined by the inability of 80 percent of the children to access the number of units which produce toxicity, or to access "more than eight" (9 units), whichever is lower. The U.S. regulations under the PPPA differ from the position held in Europe where opaque conventional blister unit dose packaging by its very nature is considered to be "child-resistant."

The staff of the U.S. Consumer Product Safety Commission (CPSC) measured the ability of children to access conventional unit packaging. Three different unit package types were tested using standardized child test procedures defined in the PPPA (16 CFR 1700.20). The three packages tested were:

1. Conventional Blister (push through type)
2. Conventional Pouch (tear open type)
3. Child-Resistant Blister (peel - push through foil, ASTM Type VIII)

In each test, 96 to 100 children were given unlimited packages for two 5-minute test periods. In addition, they were told they could use their teeth if they wanted to.

The number of units that corresponds to approximately 80 percent child-resistant effectiveness was determined to be 30 conventional pouch units, 31 conventional blister units or 4 child-resistant blister units.

The test results demonstrate that various designs of unit packaging provide substantially different resistance to child access. The child access to 30 conventional pouch and 31 conventional blister units would not permit these two types of conventional unit packaging to comply with the current requirements for child-resistance in the United States, which prohibits access by 80 percent of children to more than 8 units.

INTRODUCTION

The Poison Prevention Packaging Act of 1970 (PPPA) authorizes the U.S. Consumer Product Safety Commission (CPSC) to promulgate child-resistant packaging standards to protect children from serious injury or illness resulting from handling, using or ingesting hazardous substances. The Commission determines which household substances must be contained in child-resistant packaging. However, the PPPA prohibits the Commission from specifying child-resistant packaging designs.

Child-resistant packaging is defined by the PPPA as packaging that is designed or constructed to be difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance in the packaging within a reasonable time, and not difficult for normal adults to use properly (16 CFR § 1700.1(4)). Accordingly, child-resistance and adult-use effectiveness are defined by performance standards. Test methods using human subjects were developed to determine the effectiveness of a package. When tested according to these methods, packages must have 90 percent adult-use-effectiveness and 80 percent child-resistance. These test methods and standards apply to all packages that contain a regulated substance including unit packaging.

Unit packaging is packaging that allows access to one dosage or usage unit at a time. This type of packaging can hold solid, liquid, or powdered pharmaceutical or general household products. Unit packaging that holds pharmaceutical products is generally referred to as unit dose packaging because each "unit" holds a dosage of the drug which is accessed separately. Most unit packaging is nonreclosable. The common types of nonreclosable unit packaging are pouches, blisters, and strips.

The testing of unit packaging for child-resistance is generally conducted the same way as for reclosable packaging. The child test method is specified in the PPPA regulations (16 CFR § 1700.20).

A failure for unit packaging during a child test is defined as access by the child to the number of units that constitutes an amount that would cause serious injury or access by the child to more than eight units, whichever is less. This differs from the position held in Europe where opaque conventional blister unit dose packaging is considered to be "child-resistant" by its very nature.

The staff of the CPSC measured the ability of children to access conventional unit packaging. Two conventional and one "child-resistant" unit package types were tested using standardized child test procedures. The package descriptions, test methods, results, and discussion of the comparison of the ability of children to access the different package types are described below.

PACKAGE DESCRIPTIONS

Conventional Pouch Packaging

A conventional pouch was used in the testing[1]. The pouch (Picture 1) had the following characteristics; dimensions of 2-1/2" x 2", constructed of paper/plastic/foil/plastic, with an EZ open corner tear notch opening feature (tears easily), four sided 1/4" heat seals, and contained placebo gelcaps (caplets).

Conventional Blister Packaging

A conventional blister was used in the testing[2]. The blister (Picture 1) had the following characteristics; dimensions of 2-5/8" x 3-3/4", product pattern of 2 x 5 x 1 for a total of 10 capsules per blister card, constructed of plastic blister film and coated foil backing, conventional push through type opening feature. Each blister cavity contained one placebo capsule. The push through opening force for this blister averaged 6 lbs (1.9 standard deviation (SD)) with a range of 2-11 lbs.

Child-Resistant Blister Packaging

A child-resistant blister card was used in the testing[3]. The ASTM[4] Type III D blister (Picture 11) had the following characteristics; dimensions of 1-3/4" x 3", product pattern 2 x 3 x 1 for a total of 6 oval shaped tablets per card, each unit was separated by perforations, constructed of plastic blister film and paper/plastic/foil/plastic backing. The tablet is removed from the cavity by tearing at perforations, peel back and push through foil type opening feature. Each blister cavity contained one placebo oval shaped tablet.

TEST PROCEDURES

The three packages described above were tested according to the basic PPPA test parameters described in the regulations, (16 CFR § 1700.20) including the restriction on the number of children tested at each site (20%), the restriction on the number of children tested by each tester (30%), and the calculation and distribution of the age groups (30% age 42-44 months, 40% age 45-48 months, 30% age 49-51 months). Since additional information was collected during these tests the specific test method is described in Appendix A.

Two sequential tests of 50 children each (total of 100 children) were conducted using the different unit packaging. The only exception was the conventional pouch packaging which was tested with a total of 96 children due to a shortage of samples.

The purpose of the tests was to measure the ability of the children to access the packages during the timed test period. The children were given unlimited packages to open during the 10 minute test period. The presentation of each package type is described in Appendix A, procedure 10.

During the test, children were given a demonstration if one or both children tested did not open a single package during the first 5 minute test period. Children were told they could use their teeth if one or both of the children had not used their teeth during the first 5 minute time period.

Testers recorded the opening time for the first unit. In addition, they noted if children were given a demonstration and were told to use their teeth.

Following the testing, the tested samples were analyzed to determine the number of units accessed and the method of access.

RESULTS

Conventional Pouch Packaging

Test results with the pouches show that 100 percent of the children were able to open one pouch during the 10-minute test period. The average time to open the first unit was 43 seconds (SD 75). The average number of pouches opened by the children was 20 (SD 11). Table 1 provides the distribution of pouch openings for the different ages of children (1-54 pouches accessed). The percentages of children able to open each number of pouches during the 10-minute test period is also presented.

Conventional Blister Packaging

Test results with the conventional blisters show that 93 percent of the children were able to open one blister during the 10-minute test period. The average time to open the first blister was 169 seconds (SD 134). The average number of blisters opened by the children was 23 (SD 14). Table 2 provides the distribution of blister openings for the different ages of children (0-85 blisters accessed). The percentages of children able to open each number of blisters during the 10-minute test period is also presented.

Table 1: Child Unit Dose Protocol Test. Number of Conventional Pouches Opened By Children in 10 minutes

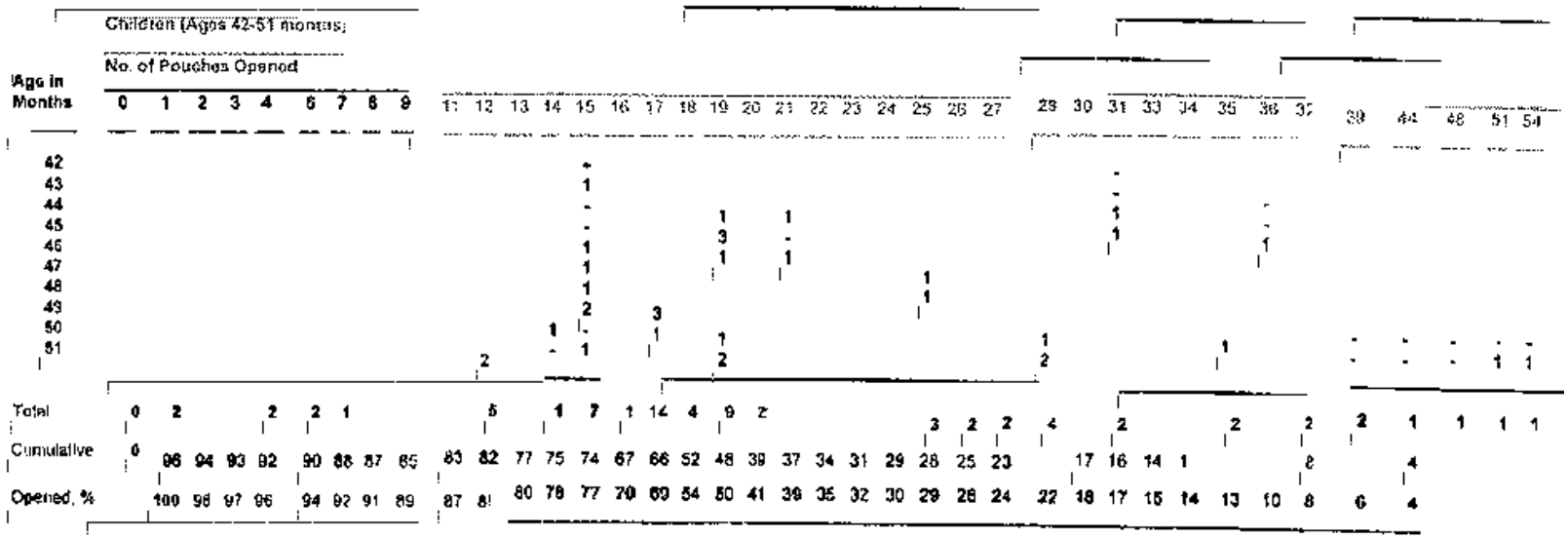
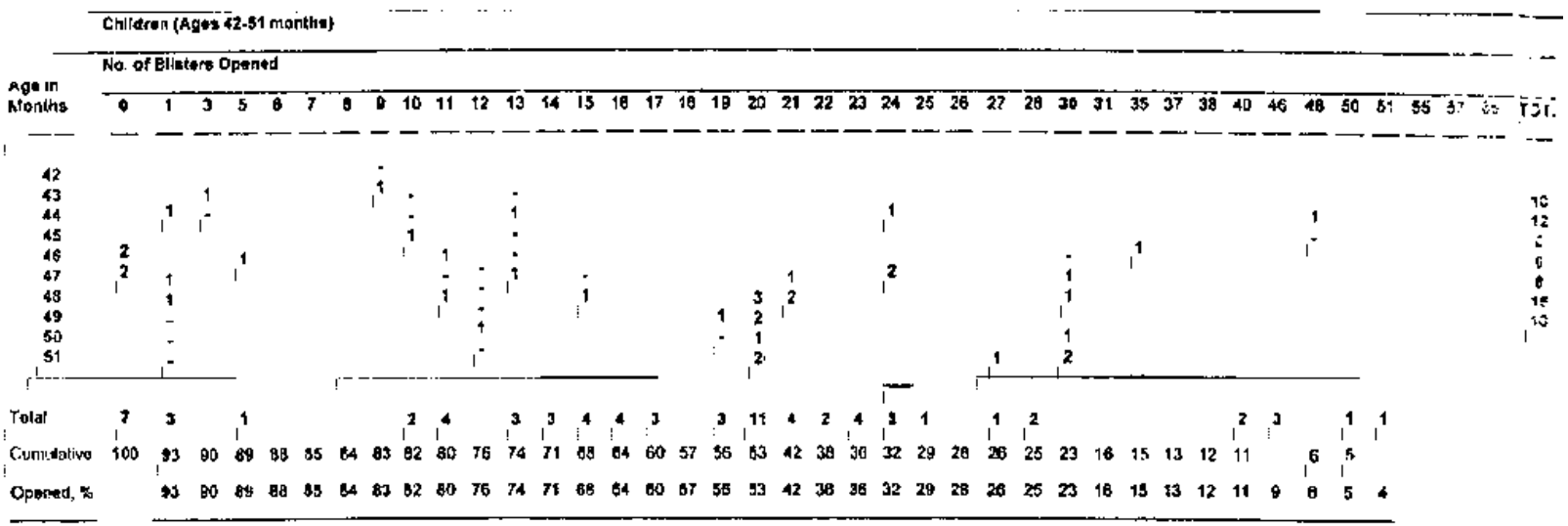


Table 2: Child Unit Dose Protocol Test Number of Conventional Blisters Opened By Children in 10 minutes



Child-Resistant Blister Packaging

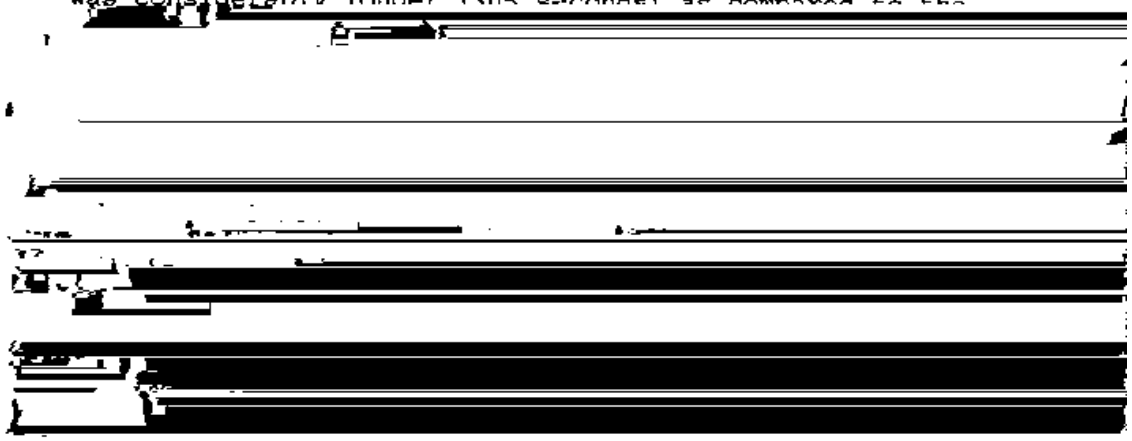
Test results with the child-resistant blisters show that 53 percent of the children were able to open one child-resistant blister during the 10-minute test period. The average opening time was 305 seconds (SD 153). The average number of child-resistant blisters opened by the children was 3 (SD 2). Table 3 provides the distribution of child-resistant blister openings for the different ages of children (0-8 units accessed). The percentages of children able to open each number of units during the 10-minute test period is also presented.

DISCUSSION and CONCLUSIONS

A comparison of the three package types shows that, as predicted, there is a demonstrated difference in the ability of young children to gain access to the conventional blister and pouch packaging versus child-resistant blister packaging during the 10-minute test period (**Graph I**). The child-resistant blister package is designed to limit access by young children to harmful amounts of products on the market. This is in contrast to both the conventional blister and pouch packaging which performed similarly and can both be readily opened by children 42-51 months of age.

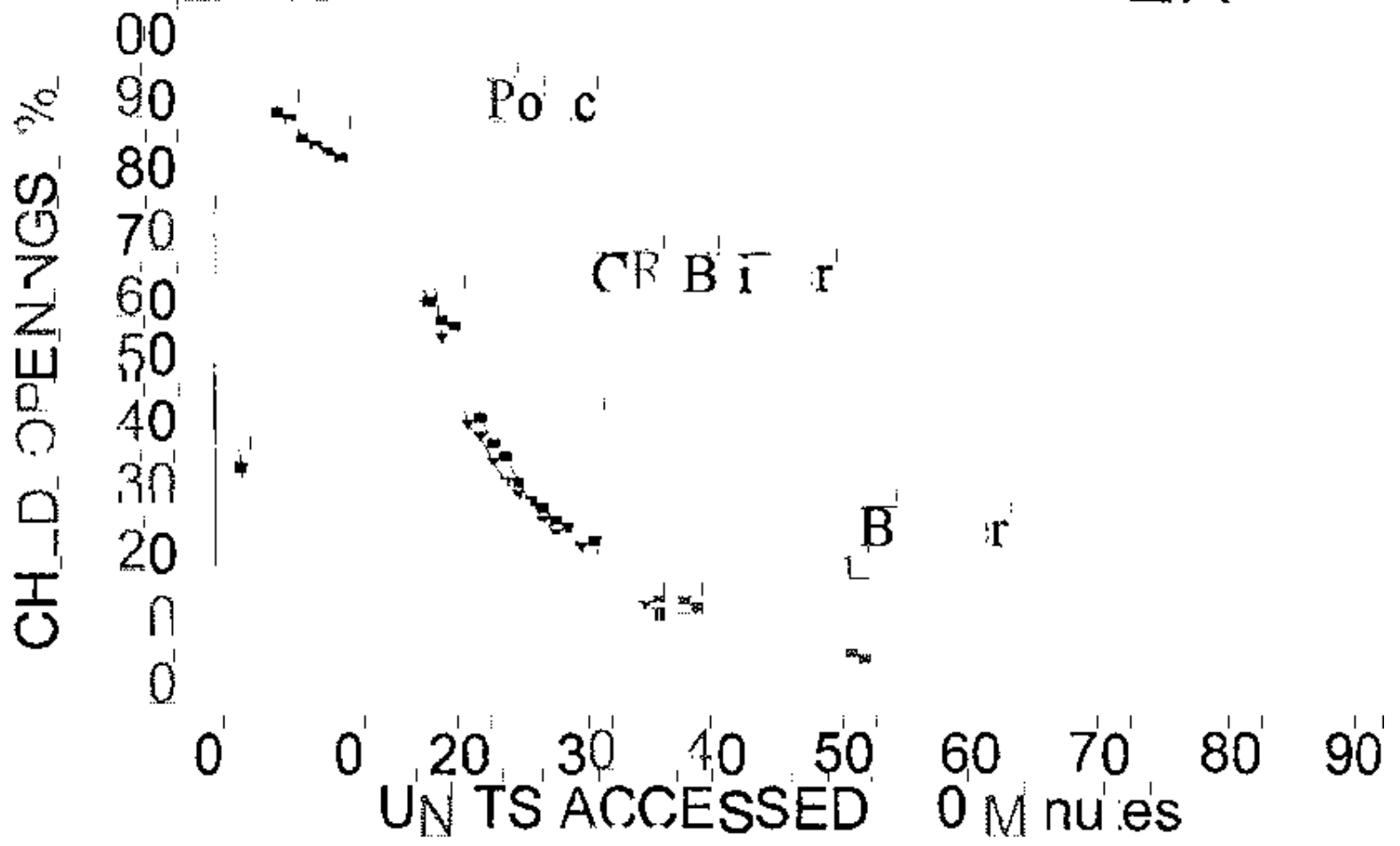
The percentage of children who can open one unit is an index of the acceptability of various types of unit dose packaging. When comparing the results for the first opening, fewer children could access the child-resistant blister (53%) compared to the conventional blister (93%) or the pouch (100%). It should be noted however, that there are other child-resistant packaging designs that can further limit children's access to units[4]. The choice of a particular design of child-resistant unit packaging depends on the level of protection needed to prevent serious injury to a small child.

The time to open one unit is also a gauge of the level of protection afforded young children. The longer it takes to open the package, the greater the likelihood that a parent will find the child and remove the product before an ingestion can take place. The average time needed to open a child-resistant blister was considerably longer (305 seconds) as compared to the



GRAPH I UNIT DOSE PACKAGING

POUCH BI STER & CR BL STER



The number of units that corresponds to 80 percent child-resistant effectiveness was calculated. This was determined to be 30 conventional pouch units, 31 conventional blister units or

The test results demonstrate that various designs of unit

access. A child-resistance of 4 units would make this type of

SUPPORTING DOCUMENTS

1. Tewabe, A., Wilbur, C., Laboratory Report, Form 221, Conventional Pouch, 2" x 2.5", construction-1 lb Over-coat/ 26 lbs CIS Pouch Paper/7.5 lbs LDPE/.00035" Foil/15 lbs LDPE, Heat Sealed four sides, with EZ Open Corner slit, and two (Placebo) gelcaps(caplets) per pouch, 97-594-0297, No. 2938, CPSC, Health Sciences, June 12, 1997.

2. Tewabe, A., Wilbur, C., Laboratory Report, Form 221, Conventional Blisters, 2-1/8" x 3-3/4", product pattern 2 x 5 x 1=10 Capsules/card, Push Through Type, 0.002 foil, 6 lbs Crystal Clear rigid homopolymer vinyl blister film and Reynolds Drug Pak No. 501-.001"aluminum foil with modified vinyl heat seal coating on foil bright side backing material, 97-594-0290, No. 2925, CPSC, Health Sciences, June 4, 1997.

3. Tewabe, A., Wilbur, C., Laboratory Report, Form 221, CR Blister ASTM Type VIII D, Peel Push Through Foil Type, 1-3/4" x 3", Product pattern, 3 x 2 x 1=6 tablets with removal perforations, construction-10 mil PVC blister film and Reynolds 216 backing material, 98-594-0367, No. 3029, CPSC, Health Sciences, October 92, 1997.

4. ASTM, Standard Classification Child-Resistant Packages D-3475, ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Telephone 610-832-3739.

APPENDIX A

CHILD TEST FOR UNIT DESIGN

Test Procedures

1. Each child's parent or guardian shall read and sign a consent form prior to participation by that child.

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. The children 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.

4. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions. A box to hold loose package contents shall be available.

5. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the children so that there is no visual barrier between the children and the tester.

6. The tester shall talk to the children to make them feel at ease.

7. 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.

8. 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. The only EXCEPTION is to record the test time to open the first unit.

9. The tester shall use a stopwatch(s) or other timing device to record the number of seconds it takes the child to open the first unit and to time the 5-minute test periods.

10. To begin the test, the tester shall hand the children

Conventional Pouch Packaging

The children were presented with 15 pouches (2 caplets/pouch). The child/children were given 2 more pouches when the child/children had accessed all the caplets available or when they had done all they could do with the pouches even if a caplet remained (for example, partial removal). This was repeated as necessary, 2 additional pouches at a time until the 10 minutes had past.

Conventional Blister Packaging

The children were presented with 4 cards (10 capsules each for 40 capsules total). The child/children were given a 5th card when the child/children had accessed all the capsules available or when they had done all they could do to the cards even if a capsule remained (for example, partial removal or pulverized capsule). Additional cards were given as necessary until the 10 minutes had past.

Child-Resistant Blister Packaging

The children were presented with 2 cards (6 tablets each for 12 tablet total). The child/children were given a 3rd card when the child/children had accessed all the tablets available or when they had done all they could do to the cards even if a tablet remained (for example, partial removal or pulverized tablet). Additional cards were given as necessary until the 10 minutes had past.

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(s) on 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.

Each child shall be given five minutes to open as many of his/her unit packages as they can. The tester shall watch the children at all times during the test. The tester shall minimize conversation 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 - packages, the tester shall reassure the child and gently encourage the child to keep trying (e.g., "please try to open the package").

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, bang or pry the package).

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.

15. 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.

16 A child shall not be allowed to try to open the other child's packages.

17 If a child opens one of his/her units, the tester shall record the time to open the first unit in seconds on the data sheet. All children shall continue to open packages for the full ten minute (two 5-minute) time period.

18 At the end of the first 5-minute period, the tester shall stop the test. The tester shall ask the children to set their packages aside.

19 If one or both children have not opened a single unit the tester shall demonstrate how to open the package. A separate "demo" package, identical to the child's package shall be used for the demonstration. The children shall not be allowed to continue to try to open their packages during the demonstration period. The tester shall say "WATCH ME OPEN MY PACKAGE." 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 be using the contents. There shall be no exaggerated opening movements. The tester shall not discuss or describe how to open the package.

If both children have opened at least one unit before the end of the first 5-minute test period, no demonstration is given. Instead, the tester will give the children a rest of approximately one minute (to approximate the time of a demonstration).

21 If one or both children have not used their teeth to try to open their packages during the first five 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.

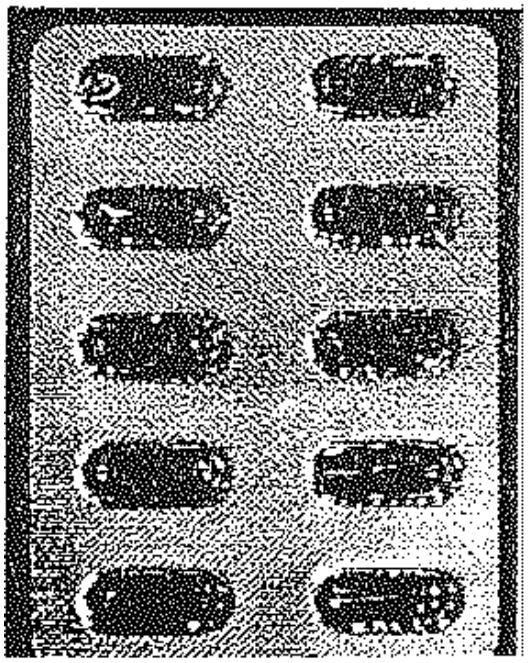
22 To begin the second 5-minute period, the tester shall say "CONTINUE TO TRY TO OPEN YOUR PACKAGES."

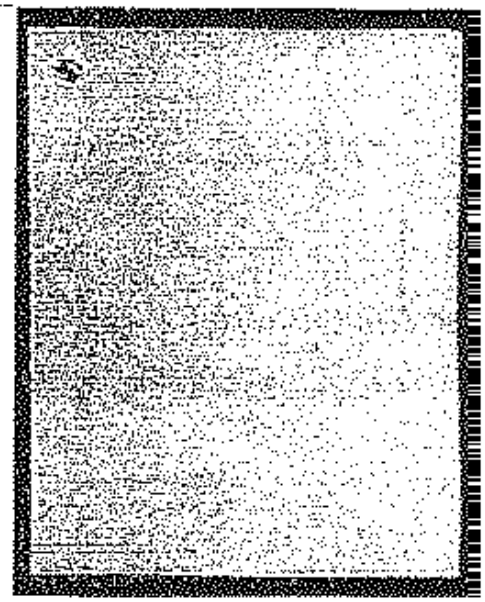
23 The test shall continue for an additional five minutes

24 At the end of the test period, the tester shall say "THANK YOU FOR HELPING." If the 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."

25 The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

PICTURE CONTINENTAL TELANDOCH





PICTURE CHILDRESISTANTBLIST