CHILD RESISTANT PACKAGING

OVERVIEW OF PROTOCOL TESTING AND CPSIA REQUIREMENTS

LORI M. DIXON, PHD
GREAT LAKES MARKETING
How does this cap know if it is a kid or an adult who wants to get the stuff out?
Goals for the Day

- Review test protocols
- Review CPSIA
“Packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of substance contained therein within a reasonable time and not difficult for normal adults to use properly.”
“Packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of substance contained therein within a reasonable time and not difficult for normal adults to use properly.”
“Every year more than one million children under 5 years of age are exposed to poisonous household chemicals and medicines, and an estimated 30 children die as a result of these accidental poisonings.”
## Child Data Sheet

<table>
<thead>
<tr>
<th>Package</th>
<th>GLM Job Number</th>
<th>Site Code</th>
<th>Test Area</th>
<th>Test Date</th>
<th>Tester</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Package</th>
<th>Birthdate</th>
<th>Sex</th>
<th>Age</th>
<th>Military Time</th>
<th>Open ed &amp; Hot Speed</th>
<th>Method to Open or N</th>
<th>1 = Yes 2 = No</th>
<th>Used Teeth</th>
<th>Order</th>
<th>Tester Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Month</td>
<td></td>
<td></td>
<td>Hour</td>
<td>Movie</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Package</th>
<th>60 sec prompt</th>
<th>1 = Yes 2 = No</th>
<th>First 5 min additional prompts</th>
<th>Second 5 min total prompts</th>
<th>Test Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Method:
- 50 Normal Opening
- 51 Shelled Upper Cap
- 52 Pried Closure OFF
- 53 Broke Closure
- 54 Teeth

Tester Comments:
- 10 Used teeth, but did not open with teeth
- 18 Observers present
- 46 Asked for tool

Tailled by [ ]
Entered by [ ]

Unintelligible data within child data.
“… 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 …”
# Unit Dose Data Collection Form

## Child Unit Dose Data Sheet

<table>
<thead>
<tr>
<th>Package</th>
<th>Birthdate</th>
<th>V</th>
<th>Age</th>
<th>Sex</th>
<th>Military Time</th>
<th>Open Method</th>
<th>Order</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pkg. No.</th>
<th>60 sec prompt</th>
<th>First 5 min additional prompts</th>
<th>Second 5 min. total prompts</th>
<th>Test Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statement made: “You can use your teeth if you want to.”*

## Method:
- 50: Normal Opening
- 54: Teeth
- 55: Other (Specify in tester comments)

## Tester Comments:
- 10: Used teeth, but did not open with teeth
- 26: Separated some sections
- 27: Separated all sections

*Entered by [ ]*
Children must be 42-51 months in age (using near age calculations).

- 30% 42-44 mos of age;
- 40% 45-48 mos of age;
- 30% 49-51 mos of age.

- 50% male/female
Child Panel Requirements

- Can only test two packages and must be of different ASTM types.
- No more than 20% from one site.
- No more than 30% by one tester.
- No overt handicaps
- (Can go without a potty break for 10 minutes!)
Test two children at same time.
Say “please try and open this for me.”
If they stop, say “please try to open the package.”
Give them 5 minutes.
Ask them to stop working on the package.
Child Panel Requirements

- Give demonstration.
  - No words.
- Say, “now you try to open your package.”
- Say, “you can use your teeth if you want to.”
- Give them 5 more minutes.
- Give them grandma lecture.
<table>
<thead>
<tr>
<th>Panel Size</th>
<th>First Five Minutes</th>
<th>Second Five Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pass</td>
<td>Continue</td>
</tr>
<tr>
<td>50</td>
<td>0-3</td>
<td>4-10</td>
</tr>
<tr>
<td>100</td>
<td>4-10</td>
<td>11-18</td>
</tr>
<tr>
<td>150</td>
<td>11-18</td>
<td>19-25</td>
</tr>
<tr>
<td>200</td>
<td>19-30</td>
<td>--</td>
</tr>
</tbody>
</table>

- **90%** for 50-panel size
- **80%** for 200-panel size
CHILD RESISTANT

Not child proof
Senior–Adult Panel Requirements

- Ages 50-70
  - (25% 50-54; 25% 55-59; 50% 60-70).
- 70% female in each age category.
- No more than 24% per site and no more than 35% per tester.
- No more than two packages per sitting (must be different ASTM types).
Data Collection Form

Senior Adult Testing Data Collection Form

Thank you for your help today. Please read and sign this consent form. Just to verify, you are ___ years of age as of today?

Date of Birth:__/__/___

Check: 200 - 54  55 - 59  60 - 70  Check: Male  Female  Pkg. No. ___

"I'm going to ask you to open and close two identical packages according to the instructions on the cap."

"Please open this according to the instructions on the cap."
"Please pour out a few of the beans."

Open A
Seconds: ___

If the person stops, check here ☐ and say, "Are you finished with that package or would you like to try again?"

IF NOT OPENED: Check here ☐ put seconds tried on line ______ and fill out box below.

"Please close the package properly."
If not closed, put 300 on seconds line and explain:

Close A
Seconds: ___

"Here is an identical package. Please open this according to the instructions on the cap."
"Please pour out a few of the beans."

Open B
Seconds: ___

If the person stops, check here ☐ and say, "Are you finished with that package or would you like to try again?"

IF NOT OPENED: Check here ☐ and put seconds tried on line ______

"Please close the package properly."
If not closed, put 300 on seconds line and explain:

Close B
Seconds: ___

Now, how would you rate using this second package on this scale of 1 - 5 where 1 is very easy for YOU to use and 5 is very hard for YOU to use?  1 2 3 4 5

Hand respondent snap cap: Please open and properly close this package. Seconds: ___

Hand respondent CT cap: Please open and properly close this package. Seconds: ___

Sensor read directions?  1 Yes, quickly  2 Yes, very carefully  3 No, did not read
Sensor appeared to understand directions and what to do?  1 Yes  2 No
Appeared to perform proper motions to open container?  1 Yes, definitely  2 Yes, somewhat  3 No
Was physically too weak to open the container correctly?  1 Yes  2 No
Completed of illness or injury?  1 No  2 Yes - Explain:
Other comments (Explain exactly what the person did try to try and open):

Date: __/__/___  Age: ___________  Time: ___________  Tester: ___________

Signed by: ___________ Date: ___________ Entered by: ___________ Date: ___________
Intercept “normal” adult.

Ask them to “read and sign the consent form.”

Say, “I am going to ask you to open and properly close these two identical packages according to the instructions found on the ____.”

“This is the best physical therapy medical science has ever devised. The childproof cap!”
If they stop, say “are you finished with that package or would you like to try again?”

After they open it, say, “please empty the ____ into this container.”

Say, “please close the package properly, according to the instructions on the ____.”
If they open and close the package, take it from them.

Hand them a new package and say, “This is an identical package. Please open it according to the instructions on the ___.”

Repeat next two commands.

Rate ease of opening.
If they do not open the first package, hand them a non-CR snap and say, “please open and properly close this package.”

Hand them a non-CR continuous thread package and say, “please open and properly close this package.”

They have 60 seconds to open & close.
Calculating Failures for Senior Panel

- For reclosable packages: They must open the first package within five minutes and open and properly close the second package in one minute.
- For unit dose packages: They must access one unit within five minutes from the first package/card and one unit in one minute from a new package/card.
Panel members who cannot open the first package and cannot open the non-CR screening packages are not included in the panel and are not counted as failures.

If they open the first package but not the second package they are counted as failures.
Calculation of SAUE

- All seniors who open and appear to close the second package in 60 seconds are counted as successes.
- Successes/100 = SAUE for non-reclosable.
- **If reclosable**, the children verify the closing. (Senior Effectiveness - child failures over 20% = SAUE.)
- 90% is minimum effectiveness.
Package Preparation

- Shelf packaging is removed.
  - Only immediate package is tested.
- All tamper evident materials are removed.
- CT caps are applied at “same on-torque as applied on the packaging line.”
- Reclosable packages must be assembled 72 hours prior to testing.
Package Preparation

- We recommend packages be filled with beans or liquid.
- If product-specific packaging for liquid, we recommend filling with similar liquid (i.e., mouthwash).
- Placebos are preferred.
- Unit dose placebos should be same size and strength (*color does not appear to matter*).
If a tool is available with the package (at retail level) it is provided to adults and children.

If a tool is pictured, but not supplied, it is made available to the adults, **not** the children.

Adults are discouraged from using “tools” they carry, but can use them. (Notes are made on the data sheet.)

“Honey, I got the lid off the bottle of aspirin.”
Instructions

- All instructions available with the package are given to the respondents (inc. outer box instructions and inserts).

- For prototypes, instructions should match final concept in size/color/font.

“Please keep trying, Mr. Fuller. We can’t discharge you until you prove to us that you can open a child-proof cap.”
Full protocol: Reclosable

- 100 senior panel = 200 units and extras
- 50 child panel = 50 units plus demo packages and extras
Number of Packages Needed

Full protocol: Unit Dose

- 100 senior panel = 200 cards/pouches and extras
- 50 child panel = 50 toxic doses* plus 25 demos and extras

*(each kid needs access to toxic level or 9 pills)
Drugs currently included in 16 CFR § 1700.14

- acetaminophen
- aspirin
- controlled drugs
- dibucaine
- diphenhydramine
- ibuprofen
- iron-containing drugs and dietary supplements
- ketoprofen
- lidocaine
- loperamide
- methyl salicylate
- minoxidil
- mouthwash
- naproxen
- oral prescription drugs
- OTC switch drugs
Substances currently included in 16 CFR § 1700.14

- ethylene glycol
- fluoride
- furniture polish
- glue removers containing acetonitrile
- hydrocarbons
- kindling and/or illuminating preparations
- methacrylic acid
- methyl alcohol
- mouthwash containing ethanol
- permanent wave neutralizer containing sodium or potassium bromate
- sodium and potassium hydroxide
- solvents for paint or other coating material
- sulfuric acid
- turpentine
Exceptions

- Not used in/around the household
  - Institutional use
    - Hospitals, nursing homes
  - Professional use
Exceptions (cont.)

- Prescription
  - Bulk Drugs repackaged by the pharmacist
  - Requested by patient or physician
  - Exempted (16 CFR § 1702)
    - 16 CFR §1700.14(a)(10)(i)-(xxi)
Exceptions (cont.)

- OTCs - Household Products
  - One size
  - Labeled (16 CFR §1700.5)
    - “This Package For Households Without Young Children”
    - “Package Not Child-Resistant”
  - Other popular sizes are CR
  - Imposed exclusive CR
  - Drain cleaners (16 CFR 1500.17)
Metal cans/metal closures and aerosols.

- Use 100 adults aged 18-45 years
- One 5 minute time period
- 90% effectiveness
CPSIA

- Certificate of Conformity
  - Handouts
- Not needed for empty packages
- Third party testing is NOT required
  - “Certificate must be based on some type of test.”
- Bracketing is allowed
- “May change and require a “reasonable” testing program.”
- “May require remedial plan.”
QUESTIONS?