

Child Resistant Packaging

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Review of Testing Protocols

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**GREAT LAKES
MARKETING
RESEARCH** 



**LABORATORY
ACCREDITATION
BUREAU** a division of A-S-B
ACCREDITED ISO/IEC 17025

16 C.F.R. 1700

In January 2016, the President of the United States signed the Child Nicotine Poisoning Prevention Act of 2015 into law

U.S. CONSUMER PRODUCT SAFETY COMMISSION



Office of Compliance

Requirements¹ under the Poison Prevention Packaging Act, 16 C.F.R. 1700

- The CPSC oversees the packaging for liquid nicotine
- The FDA oversees the delivery system (including the cartridges)

Poison Prevention Packaging Act

Purpose

- To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting hazardous **household substances**.




One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION


*Begun and held at the City of Washington on Monday,
the fourth day of January, two thousand and sixteen*

An Act

Child Nicotine Poisoning Prevention Act of 2015

-  This bill requires any nicotine provided in a liquid nicotine container sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States to be packaged in accordance with the Consumer Product Safety Commission's (CPSC's) standards and testing procedures for special packaging that is difficult for children under five years of age to open or to obtain harmful contents from.
-  "Liquid nicotine container" is defined to:
 - (1) Include a package from which nicotine in a solution or other form is accessible through normal and foreseeable use by a consumer and that is used to hold soluble nicotine in any concentration; and
 - (2) **Exclude** a sealed, pre-filled, and disposable container of nicotine in a solution or other form in which such container is inserted directly into an electronic cigarette, electronic nicotine delivery system, or other similar product, if the nicotine in the container is inaccessible through customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion or other contact by children.
-  The bill applies to any form of chemical nicotine, including any salt or complex, regardless of whether the chemical is naturally or synthetically derived.


Special Packaging

-  “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.”

CPSC Standards and Testing


- Requires testing in accordance with the method described in section **1700.20 of title 16, Code of Federal Regulations**, and any subsequent changes to such sections adopted by the Commission.
- A link to this is on GLM.com under the tab for Child Resistant Package Testing


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We provide answers to your marketing questions






Child Resistant PACKAGE TESTING

We test packages with hundreds of children and senior adults each week. We have contracts with the U.S. Consumer Product Safety Commission (CPSC) and have been audited by the Canadian Standards Association.

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Great Lakes Marketing Research

Since 1964 Full-Service Marketing Research Firm

Child-Resistant Testing

Great Lakes Marketing is an independent, ISO 17025 accredited child-resistant testing facility. We have been testing safety packaging and lighters for over 35 years to make sure that packaging is safe for household use. We test packaging with hundreds of children and adults each week. GLM has been contracted by U.S. Consumer Product Safety Commission (CPSC) and audited by the Canadian Standards Association. We are a leader in the field of child-resistant packaging and are proudly working to ensure the safety of small children.

What We Do

Great Lakes Marketing is ISO 17025 accredited to perform child-resistant testing of packages, lighters, pesticides, bait stations, and portable fuel containers, according to the following standards:

Packages

- [16 CFR 1700](#) – Standard for Packaging used by CPSC
- [ISO 8317](#) – International Standard for Reclosable Packaging
- [EN 14375](#) – International Standard for Non-reclosable Pharmaceutical Packaging
- [CAN/CSA Z76.1](#) – Canadian Standard for Reclosable Packaging

Lighters

- [16 CFR 1210](#) – Standard for Cigarette Lighters used by CPSC
- [16 CFR 1212](#) – Standard for Multipurpose Lighters used by CPSC
- [EN 13869](#) – International Standard for Lighters

Getting Ready

Decisions

- Package preparation
 - Placebo
 - Torque
- Opening directions

Timing & Budget

- 4 to 6 weeks
- Typically under \$10,000 for a full test
- Deliverables

Child Panel

Requirements & Protocol

Child Panel Composition

- Children must be 42-51 months in age (using near age calculations)
 - 30% 42-44 months of age
 - 40% 45-48 months of age
 - 30% 49-51 months of age
- 50% male / 50% female
- Can test two packages/different ASTM types
- No more than 20% from one site
- No more than 30% by one tester
- *(Can go without a potty break for 10 minutes!)*



Child Panel Testing Protocol

- **“Please try to open this for me”**
- Time a 5-minute period
- After 5 minutes, ask them to stop working on the package
- **“Watch me open my package.**
- Demonstrate (visually only) how to open the package.
- **Now you try to open your package.**
You can use your teeth if you want to”
- Time second 5-minute period
- Give them *grandma lecture*



Tested in pairs

Child Panel Pass/Fail Criteria

Panel Size	First 5 Minutes			Second 5 Minutes		
	Pass	Continue	Fail	Pass	Continue	Fail
50	0-3 94%	4-10	11+	0-5 90%	6-15	15+
100	4-10	11-18	19+	6-15	16-24	25+
150	11-18	19-25	26+	16-25	26-34	35+
200	19-30	-	31+	26-40 80%	-	41+

Child resistant,
not child proof!



Will he get it open?

80% pass is acceptable

Senior Panel

Requirements & Protocol

Senior Panel Composition

- 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 35% per tester
- No more than two packages per sitting
 - Must be different ASTM types



Senior Panel Testing Protocol

- Request help from a normal adult
- Read and sign a consent form
- **“I am going to ask you to open and properly close these two identical packages **according to the instructions found on the _____**”**
- If they stop, say **“Are you finished with that package or would you like to try again?”**
- 5 minutes for first package





Senior Panel Testing Protocol

(continued)



- **“Please empty the ____ into this container.”**
 - **“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 repeat opening and closing
 - 60 seconds for second package
 - Rate ease of opening
-
- If the first package is not opened, they have 60 seconds to open & close regular packages. Those failing are excluded from the panel.

Calculating Failures for Senior Panel




-  Not opening first package in 5 minutes
-  Not opening and closing second package in 1 minute

Calculation for Passing Rate

Single Dose


-  Open the second package in 60 seconds = success
-  $\text{Successes} / 100 = \text{SAUE}$


Recloseable

-  Open and close the second package in 60 seconds = success
-  The children verify the closing (Senior successes - child failures over 20% = SAUE)
-  90% is minimum effectiveness



SAUE Calculation





Results

-  3 Seniors did not open the second package

-  27 children open the package

Calculation

-  97 Packages are given to the children
-  20% of the packages opened by children fall in the acceptable range (19.4)

-  This is 7.6 more than acceptable
-  7.6 child failures plus 3 senior failures = 10.6 failures
-  $100 - 10.6 = 89.4\%$
-  Pass requires 90%

Package Preparation

- Shelf packaging is removed/all tamper evident materials are removed
- Threaded caps are applied at “same on-torque as applied on the packaging line”
- Threaded caps must be assembled 72 hours prior to testing
- Packages should be filled with placebo

Use of Tools

- If a tool is available with the package (at retail level):
 - Provide to adults and children during test
- If a tool is pictured, but not supplied:
 - Provide to adults, **not** children





Instructions

- All instructions available with the package are given to the respondents (including outer box instructions and inserts)
- For prototypes, instructions should match final concept in size/color/font



Number of Packages Needed

Full Protocol: Reclosable

-  100 senior panel = 200 units and extras
-  50 child panel = 50 units* plus demo packages and extras

*Unit = toxic dose

FAQ

- Bracketing sizes?
Reasonable testing program
- Package preparation must be documented
- Testing can stop when it appears to be failing?
- Sequential panels?
- Resecuring AND a child panel?
- Third party testing?
- Accredited?
- Testing labs?



Lessons Learned

■ Cigarette Lighters/ Multi purpose lighters

- Novelty lighters
- Visually appealing

■ Laundry Packets

- Poison stats
- Voluntary



E-Cigarettes and Liquid Nicotine



Liquid nicotine exposures continue to concern poison specialists.



National Poison Prevention Week

-  “Every year more than 1 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.”
-  “*The researchers say the results highlight a need for better parent awareness about the importance of keeping the devices out of sight and reach of young kids.*”

CPSC Contacts

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Questions/Documents?

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