

# Poison Prevention Packaging Act

Unit Packaging

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# Unit Packaging

- Packages that contain single dosages or usages.



# What To Test

- The package configuration that results in the “worst-case scenario”
- Units in the form in which they will enter the home
  - Example: Do not test separated units if the units will enter the home as an intact group of units, unless testing separated units presents the worst-case scenario

# What To Test (continued)

- The number of units that the consumer will typically bring into the home at one time
- Tools
  - The tool should be given to children, if the tool will be provided to consumers with the package.
  - The tool should be provided for adults if instructions are given to use a tool.

# Definition of Test Failure

- When conducting the test for child resistance on a unit package, a test failure shall be a 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
  - more than 8 individual units,whichever number is lower during the full 10 minutes of testing.
- See 16 C.F.R. §1700.20(a)(2)(ii)

# Opened / Gained Access To

- Interpreted as the individual units from which the product has been removed or can be removed in whole or in part.

# Opened / Gained Access To

(continued)

- Example: A blister is breached. Even if the contents are not removed, this should generally be considered access.



# “F Values”

- The number of individual units to which access is considered a test failure is commonly and unofficially referred to as “F”
- Example: If the toxicity of a substance requires access to 3 units to be considered a test failure, the substance is said to require an F=3 package.

# Determining “F”

## Serious Injury / Serious Illness

- The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound child.
- Approaches

# Toxicological Data

- Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the CPSC Office of Compliance.

# Determining “F” - Examples

- “F” is determined based on the toxicity of the contents of each unit, regardless of the number of regulated substances in the unit.

# Determining “F” - Examples

- A tablet contains two active ingredients with non-additive hazards.
  - 500 mg Drug A
    - F=3
  - 25 mg Drug B
    - F=4
- Package would be F=3 based on Drug A.

# Determining “F” - Examples

- In cases where more than one PPPA-regulated substance is packaged in one unit dose package arrangement, the failure level is determined by the most toxic unit contents.

# Determining “F” - Examples

- Multiple PPPA regulated drugs are packaged in separate blisters on a single blister card.
- If Drug A is  $F=2$ , Drug B is  $F=4$ , and Drug C is  $F=8$ . The most toxic PPPA regulated drug should determine the level of child-resistance.  $F=2$



# Determining “F” - Examples

- Some unit packages comply with the child-resistant requirements if the package contains a substance required to be packaged in an F=8 package, but fewer than 8 units are provided to consumer.
  - Example
  - Restrictions

# Reporting Test Results

- The staff recommends that unit package test results be reported so that the number of units that children access during the test is provided.
- The advantages of this include:
  - having a more complete picture of how the package performed in the test
  - having the potential to use the data to support the use of the package for other drugs of different toxicity

# Reporting Test Results (continued)

- If the number of units children access is not reported, you only know whether the package passed or failed at a certain F level.
- Example: If test data show that a package passes with a given substance at  $F=3$ , you have no way of knowing whether that package would pass if you wanted to package a similar substance requiring an  $F=1$  package in the package.

# Reporting Test Results (continued)

- The following report format examples show two ways of reporting child test results.
- Both examples report the same test results.

# Example Test Results

- The reporting examples are based on the following result of testing 50 children for 10 minutes:
  - 18 children fail to open the package or gain access to the package contents
  - 19 children access only 1 unit each
  - 8 children access a total of 2 units each
  - 5 children access a total of 3 units each
  - No children access 4 or more units

# Report Format Examples

## Example 1

<b>First panel of 50 children</b>	Children accessing 0 units	Children accessing <b>exactly</b> 1 unit	Children accessing <b>exactly</b> 2 units	Children accessing <b>exactly</b> 3 units	Children accessing <b>exactly</b> 4 units
<b>Full 10 minutes of testing</b>	<b>18</b>	<b>19</b>	<b>8</b>	<b>5</b>	<b>0</b>

## Example 2

<b>First panel of 50 children</b>	Children accessing 0 units	Children accessing <b>at least</b> 1 unit	Children accessing <b>at least</b> 2 units	Children accessing <b>at least</b> 3 units	Children accessing <b>at least</b> 4 units
<b>Full 10 minutes of testing</b>	<b>18</b>	<b>32</b>	<b>13</b>	<b>5</b>	<b>0</b>

# Reporting Test Results – Example 1

First panel of 50 children	Children accessing 0 units	Children accessing <b>exactly</b> 1 unit	Children accessing <b>exactly</b> 2 units	Children accessing <b>exactly</b> 3 units	Children accessing <b>exactly</b> 4 units
Full 10 minutes of testing	<b>18</b>	<b>19</b>	<b>8</b>	<b>5</b>	<b>0</b>

- For an actual test report to be complete, this chart would contain columns up to “Children accessing more than 8 units.” Because no children in this example accessed more than 3 units, the additional columns would have a value of 0.

# Interpreting Test Results – Example 1

- In this format, the result for each child is shown in only one column.
- The sum of the column values equals the number of children tested (50).
- A single value cannot be taken from the table to determine the performance of the package at a given failure level.

# Interpreting Test Results – Example 1 (continued)

- To determine how the package performed at  $F=1$ , sum the number of children accessing exactly 1 unit (19 children), exactly 2 units (8 children), and so forth, to determine the total number of children in the test who accessed at least one unit.
- In this example, 32 children accessed at least one unit.

# Sequential Test Pass/Fail Table

## at 16 C.F.R. § 1700.20(a)(2)(iii)

Test Panel	Total Children Tested	Package Openings (10 minutes)		
		Pass	Continue	Fail
1	50	0-5	6-14	15+
2	100	6-15	16-24	25+
3	150	16-25	26-34	35+
4	200	26-40	-	41+

# Interpreting Test Results – Example 1 (continued)

- The package fails if the substance packaged requires a failure level of access to one unit ( $F=1$ ) because 32 children ( $19 + 8 + 5$  children) accessed at least 1 unit.
- If  $F=2$ , you would continue to test the package because 13 children ( $8 + 5$  children) accessed at least 2 units.
- If  $F=3$  or greater, the package would pass the test because only 5 children accessed 3 or more units.

# Reporting Test Results – Example 2

First panel of 50 children	Children accessing 0 units	Children accessing at least 1 unit	Children accessing at least 2 units	Children accessing at least 3 units	Children accessing at least 4 units
Full 10 minutes of testing	<b>18</b>	<b>32</b> (19 + 8 + 5)	<b>13</b> (8 + 5)	<b>5</b> (5 + 0)	<b>0</b>

- For an actual test report to be complete, this chart would contain columns up to “Children accessing at least 9 units.” Because no children in this example accessed more than 3 units, the additional columns would have a value of 0.

# Interpreting Test Results – Example 2

- In this report format, the results for the same child might be included in more than one column.
- A child who accessed “at least 3 tablets” also “accessed at least 2 tablets” and so forth.

# Interpreting Test Results – Example 2 (continued)

- The sum of the column values is greater than the total number of children tested in most cases.
- A value can be taken directly from the table to determine the performance of the package at a given failure level.

# Interpreting Test Results – Example 2 (continued)

- If  $F=1$ , the package fails because 32 children accessed at least 1 unit.
- If  $F=2$ , you would continue to test the package, because 13 children accessed at least 2 units.
- If  $F=3$  or greater, the package would pass the test, because only 5 children accessed 3 or more units.

# Sequential Test Pass/Fail Table

## at 16 C.F.R. § 1700.20(a)(2)(iii)

Test Panel	Total Children Tested	Package Openings (10 minutes)		
		Pass	Continue	Fail
1	50	0-5	6-14	15+
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3	150	16-25	26-34	35+
4	200	26-40	-	41+

# When to Test / Re-test

- When developing/designing a new package
- Anytime it would be reasonable to expect that the effectiveness of the package has changed
- When you receive incident reports or complaints
- When you become aware of a manufacturing or materials defect

# When to Test / Re-test (continued)

- A change in the **package** may result in a change in the child-resistance:
  - If the cavity size of the blister changes
  - If the materials used in the package change
  - If a change in the manufacturing process occursExample: cutting blades that dull over time, resulting in substantially different perforations between blisters

# When to Test / Re-test (continued)

- A change in the **substance** to be packaged:
  - If the F value of the new substance differs from that of the substance the package was tested with, and the test report does not provide enough information to determine if the package is suitable for the new substance
  - If the new substance is of a different form, size, shape, hardness, etc, such that it might affect the child-resistance of the package

**Questions ?**