

**The U.S. Consumer Product Safety Commission**

**CPSC AND THE POISON  
PREVENTION  
PACKAGING ACT**

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**These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.**

# **Poison Prevention Packaging Act**

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

# Household Substances

Customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is-

# Household Substances

(cont.)

- A. A hazardous substance as defined by the Federal Hazardous Substances Act (FHSA);**
- B. Foods, Drugs, or Cosmetics as defined by the Federal Food, Drug, and Cosmetics Act (FD&CA); or**
- C. Substances intended for use as a fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.**

**15 U.S.C. § 1471(2)**

# What is a Package?

“The term “package” means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage in or about the household...”

15 U.S.C. § 1471(3)

# PPPA Findings

**“the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance...”**

**15 U.S.C. § 1472(a)(1)**

# PPPA Findings

**“the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.”**

**15 U.S.C. § 1472(a)(2)**

# 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 the substance contained therein within a reasonable time and not difficult for normal adults to use properly..”

15 U.S.C. § 1471(4)

# Special Packaging

**“Nothing in this Act shall authorize the Commission to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(a)(2) of this Act [15 U.S.C. § 1473(a)(2)], labeling.”**

**15 U.S.C. § 1472(d)**

# **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**
    - Section 4 allows limited use of non-complying packaging 15 U.S.C. § 1473
  - **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(a)(4))

# Packaging Test Methods

- **Child Test - 16 CFR § 1700.20(a)(2)**
  - Panels of 50 children (42-51 months)
  - Tester restriction - 30% children
  - Site restriction - 20% children
  - 5 minute - demo - Teeth - 5 minute
  - Sequential Pass/Fail Table
    - 16 CFR § 1700.20(a)(2)(iii)
    - 80% after 200 children

# SEQUENTIAL TEST

Test Panel	# Children Tested	Package Openings (Full 10 minutes)		
		Pass	Continue	Fail
1	50	0-5	6-14	15+
2	100	6-15	16-24	25+
3	150	16-25	36-34	35+
4	200	26-40	---	41+

# Unit Packaging Failure

“... 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 ...”

16 C.F.R. §1700.20(a)(2)(ii)

# Packaging Test Methods

## Senior Test -16 CFR § 1700.20(a)(3)

- 100 adults (50-70 years old)
- Site restriction (24%)
- Tester restriction (35%)
- 5 minute/1 minute test period
- Screening
- 90% Effectiveness

# Packaging Test Methods

**Metal cans/metal closures and aerosols.**

- **Use 100 Adults aged 18-45 years**
- **One 5 minute time period**
- **90% effectiveness**

# Physician's Samples

- Oral prescription drugs require special packaging.  
16 CFR § 1700.14(a)(10)
- Section 4(b) of the PPPA grants physicians the authority to order non-CR packaging for their patients in the written prescription.

# Physician's Samples

(continued)

- **The Commission's policy is to not require manufacturers of regulated prescription drug samples to provide the samples in special packaging.**
  - 49 Fed. Reg. 8008 (March 5, 1984)
- **The decision to provide special packaging is up to the physician on a case by case basis.**

# Physician's Samples

(continued)

- Section 4(b) does not apply to regulated over-the-counter (OTC) drugs because they are not dispensed by the order of a licensed practitioner.
- Samples of regulated OTC drugs must be packaged in special packaging.

# **Consumer Product Safety Improvement Act (CPSIA)**

**Under Section 102 a general certification requirement has been extended to products subject to any similar rule, standard, ban, or regulation under any Act enforced by the Commission. General conformity certifications do not need to be based on testing done by a third-party laboratory. Certification must be based on a test of the product or a "reasonable testing program."**

# Does Required Special Packaging Need Certification?

**YES!**

- The PPPA requires special packaging for certain substances.
- Special packaging must meet the performance specifications of 16 C.F.R. § 1700.15.
- The importer or the domestic party that packages any substance that requires special packaging, must certify that the special packaging meets the performance specifications of 16 C.F.R. § 1700.15.

# **GENERAL CONFORMITY CERTIFICATION**

- 1. Identification of the product**
- 2. Citation to each CPSC product safety regulation applicable**
- 3. Identification of the U.S. importer or domestic manufacturer**
- 4. Contact information for the individual maintaining records of test results**

# **GENERAL CONFORMITY CERTIFICATION (cont.)**

- 5. Date and place where the product was manufactured:**
- 6. Date and place where this product was tested for compliance with the regulation(s) cited above:**
- 7. Identification of any third-party laboratory on whose testing the certificate depends:**

**For complete instructions and more information see:  
<http://www.cpsc.gov/about/cpsia/faq/elecfaq.pdf>**

# Additional Information

- **The PPPA Web Page -**  
**<http://www.cpsc.gov/businfo/pppainfo.html>**
  - **Poison Prevention Packaging Act Regulations**
  - **PPPA Guidance Documents**
  - **Further Information on the PPPA**
  - **General Information on Poison Prevention**

# **Additional Information on the CPSIA**

**[http://www.cpsc.gov/about/cpsia/  
faq/faq.html#sect102](http://www.cpsc.gov/about/cpsia/faq/faq.html#sect102)**

***Section 102 Certification and the  
Poison Prevention Packaging  
Act***

# If you have questions about PPPA:

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# Questions?