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# U.S. CONSUMER PRODUCT SAFETY COMMISSION

## Office of Compliance



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### Requirements<sup>1</sup> under the Poison Prevention Packaging Act, 16 C.F.R. 1700

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#### ***What is the purpose of the Poison Prevention Packaging Act (PPPA), the law that requires certain products to be packaged in child-resistant packaging?***

The purpose of the PPPA is to protect children under five from poisonings and deaths that occur when they open containers of hazardous products, and eat or drink the contents.



#### ***Where can I find the requirements for child-resistant packaging?***

The rules that tell you what a child-resistant package is and what products require such packaging are published in the Code of Federal Regulations in Title 16, Part 1700. Because the Commission may add new rules from time to time, we recommend that you periodically check for new or revised rules in the Code of Federal Regulations. Instructions for accessing the regulations on the web or obtaining copies appear at the end of this document.

#### ***What products require child-resistant packaging?***

The PPPA allows the Commission to set rules requiring child-resistant packaging for specific types of products customarily used in or around the household if it determines:

- 1) that those products present a risk of serious injury or serious illness to children under five who are able to open the packages of the products and drink, eat, or handle the contents, and
- 2) that technology exists or can be developed to produce child-resistant packaging for such products, that the packaging can be used with modern mass production and assembly techniques, and that the packaging will adequately protect the integrity of the product and not interfere with its intended storage or use.

To date, the Commission has issued rules that require child-resistant packaging for the following types of household products:

- 1) chemical and cosmetic products –
  - a) the following products that contain 10% or more by weight of petroleum distillates: furniture polish, and kindling and illuminating products such as lighter fluid and lamp oil,
  - b) paint solvents that contain 10% or more by weight of benzene, toluene, xylene, or petroleum distillates;
  - c) dry products such as granules, flakes or powders that contain 10% or more by weight of sodium or potassium hydroxide, and all other products containing 2% or more of these chemicals;
  - d) liquid products containing 4% or more by weight of methyl alcohol;

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<sup>1</sup> This document is a general summary of the child-resistant packaging standards and does not replace the requirements published in 16 C.F.R. Part 1700. This summary does not include all of the details included in those requirements, particularly those involved in conducting tests on packages for child-resistance. For those details, please refer to the regulation or contact the Office of Compliance.

- e) liquid products containing 10% or more by weight of turpentine;
  - f) products containing 10% or more by weight of sulfuric acid;
  - g) liquid products containing 10% or more by weight of ethylene glycol;
  - h) liquid home permanent wave neutralizers that contain more than 600 mg of sodium bromate or more than 50 mg of potassium bromate;
  - i) liquid glue removers containing more than 500 mg of acetonitrile;
  - j) liquid products containing more than 5% methacrylic acid on a weight to volume basis;
  - k) products containing more than 50 mg of elemental fluoride in a concentration that is more than 0.5% on a weight-to-volume basis for liquids and a weight-to-weight basis for solid products. Please note that drugs and dietary supplements that meet these specifications also require child-resistant packaging;
- 2) mouthwash products containing 3 grams or more of ethanol. Please note that mouthwashes that are drugs and that have 3 grams or more ethanol also require child-resistant packaging.
- 3) drugs and dietary supplements-
- a) the following products for human use that are intended to be taken orally: aspirin; prescription and controlled drugs; products containing more than 1 gram of acetaminophen, products containing 1 gram or more of ibuprofen; products containing more than the equivalent of 66 mg of diphenhydramine base; and products containing more than 0.045 mg of loperamide;
  - b) liquid products containing more than 5% methyl salicylate;
  - c) products containing 250 mg. or more of elemental iron in a concentration of 0.025% or more on a weight-to-volume basis for liquids and 0.05% on a weight-to-weight basis for non-liquids;
  - d) products containing more than 5 mg of lidocaine or 0.5 mg of dibucaine;
  - e) products for human use containing 250 mg or more of naproxen, or more than 50 mg of ketoprofen;
  - f) products containing fluoride and mouthwash containing ethanol. (See the description above.);
  - g) products for human use containing more than 14 mg minoxidil.

Each of these regulations covers the amount of the product contained in the immediate package of a single

retail sale unit. Please refer to the regulation for each specific product to learn more about exemptions and other limitations and requirements. If you have a question about whether a product offered for sale requires child-resistant packaging, the label of the product should contain information about ingredients that will help you.

### ***What is a child-resistant package?***

A child-resistant package is one that is designed or constructed to be significantly difficult for children under five to open or obtain a harmful amount of the contents within a reasonable time. The package must also not be difficult for normal adults to use properly.

For a package to be child-resistant, a total of 80% of the children tested according to the procedure summarized below must not open the package during a full 10 minutes of testing. Please check below for more information about the level of child-resistance required during the first five minutes of testing.

To make sure that adults are able to use a child-resistant package properly, 90% of adults tested have up to five minutes, and then another minute in a second test, to open and close the package so that it is child-resistant again.

### ***How do you test a package to make sure it is child resistant?***

Before starting a test, you should review the test protocol carefully to make sure that you comply with all of the testing requirements. If you choose not to test a package yourself, we recommend that you find a qualified child-testing laboratory in the United States to perform the test. A list of test firms known to the staff is available from the Office of Compliance.

The test uses at least one, and up to four, test panels of 50 children between the ages of 42 and 51 months to test child-resistant packages. Each panel is divided into 3 groups – 30 children 42 through 44 months old, 40 children 45 through 48 months old, and 30 children 49 through 51 months old. Approximately 1/2 of the children in each group must be boys. The test procedure allows a 10% variation in the number of boys and girls in each group.

Each child in the test panel must have no illness, injury, or disability that would interfere with the child's ability to test the package. No child may test more than two packages. If a child tests two packages, the packages cannot have the same design. This keeps the child from learning how to open the package.

Two children at a time participate in the test in a well-lit room that is familiar to them and is free from distractions. The tester gives each child an empty

child-resistant package, and asks the children to try to open it. Each child has five minutes to try to do this.

If a child opens the package, he or she is not tested further and that child's test is counted as a failure of the package to be child-resistant. The tester shows any child who does not open the package in the first five minutes how to do so, and also tells any child who has not tried to use his or her teeth to try to open the package that it is all right to do so. The child then has five more minutes to try to open the package. Any child who succeeds in opening it in the second five minutes is also counted as a failure of the package.

For a package to pass, at least 85% of the children tested must be unable to open it before they receive the demonstration of how it works, and 80% after the demonstration. For the first 50-child test panel, if 5 or fewer children open the package, the package passes. If 15 or more children open it, the package fails. In either case, no further testing is necessary. If 6 through 14 children in the first panel open the package, test a second 50-child panel. Depending on the results of that test, the package may pass, fail, or require more testing. Please refer to the regulation for more detail. Testing stops after a fourth panel of children, if the test has gone that far.

### ***How do you test adults?***

The test uses a panel of 100 senior adults divided into 3 groups – 25 adults 50 to 54 years old, 25 adults 55 to 59 years old, and 50 adults 60 to 70 years old. Seventy percent of the participants, age 50 to 59 and 60 to 70, must be females. The test uses senior adults because they are the group most likely to have trouble using child-resistant packaging. Thus, if senior adults are able to open and properly close a package, younger adults should have little difficulty. Each adult tested must have no obvious overt mental or physical disability.



The adults are tested one at a time. Each adult is given a package with the printed instructions that are on the package or that will accompany the package when it is sold to consumers. Each adult has up to 5 minutes to open and, if it is reclosable, to properly close the package. Each adult who is successful has one minute to open and properly close the same package again. This ensures that the package will be easy to open during continued use after the adults have first learned how to open it. Adults who are not able to open the child-resistant package in the first five-minute test are screened to see if they can open and close two regular packages that are not child-resistant in one minute. If they cannot, their results are not counted in the child-resistant package test because they have difficulty in using all packages, not just child-resistant ones.

For a package to pass the adult test, 90% of the adults tested must be able to open and properly close the package during both the 5-minute and one minute tests. The regulation also contains a test for aerosol products and metal cans that uses younger adults aged 18 to 45, instead of senior adults. Please refer to the regulation for more detail on that test.

### ***Are there any exceptions in the law for people with disabilities who have trouble using child-resistant packaging?***

Yes. Except for prescription drugs, a manufacturer may package one size of a regulated product in regular packaging that is not child-resistant. To take advantage of this option, the manufacturer must provide the product in other sizes that are child-resistant, and must label the regular package with the statement "This package for households without young children." or, for small packages, "Package not child-resistant." Please refer to the regulation for more information about the size and location of these statements on the labels of products.

For prescription drugs, the purchaser may request a pharmacist to package a prescription in a regular package, or the physician, dentist or other person who writes the prescription may specify in the prescription itself that the drug be dispensed in regular packaging.

### ***Where can I find additional information?***

You can obtain the regulations issued under the Poison Prevention Packaging Act, 16 C.F.R. Part 1700, from the Commission's Web Site at: <http://www.cpsc.gov>. For more information on the requirements contact the Consumer Product Safety Commission, Office of Compliance, Washington, D.C. 20207, telephone: (301) 504-7913, e-mail: [sect15@cpsc.gov](mailto:sect15@cpsc.gov)