

U.S. CONSUMER PRODUCT SAFETY COMMISSION



Office of Compliance

Requirements¹ for Pacifiers, 16 C.F.R. Part 1511

What is the purpose of the pacifier rule?

This rule keeps babies from choking or suffocating on pacifiers.

Where can I find the requirements for pacifiers?

The ban is published in the Code of Federal Regulations in Title 16, Part 1511

What is a pacifier?

A pacifier is an article with a nipple intended for a young child to suck on, but that is not designed to help a baby obtain fluid. A pacifier usually has a guard or shield at the base of the nipple that keeps the pacifier from being sucked completely into a child's mouth. It also has a handle or ring, usually on the other side of the guard or shield from the nipple that is used to hold or grasp the pacifier.

What does the pacifier rule require?

The rule requires that

- (1) the shield not be so small or flexible that it can be sucked into a child's mouth;
- (2) the a pacifier have no handles or other protrusions, that are long enough to force the pacifier into the child's mouth if the child falls or lies on its face;
- (3) pacifiers are labeled to warn caregivers not to tie the pacifier around the child's neck.
- (4) a pacifier not produce small parts when tested.

How do you test a pacifier's guard or shield to make sure it can't suffocate a child?

Center the nipple in opening in the pacifier test fixture (Figure 1). Pull on the nipple gradually until you reach a force of 2 lbs. Hold the 2-lb. force for 10 seconds. If the shield pulls completely through the fixture, the pacifier fails.

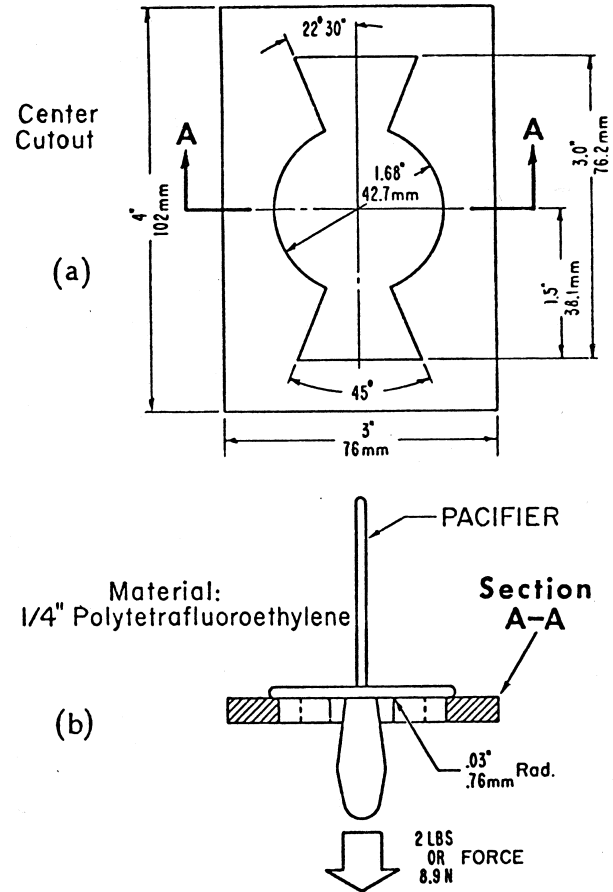


Figure 1 - Pacifier Test Fixture

Are there other requirements for shields and guards?

The pacifier guard or shield must have at least two holes, one on either side of the nipple. Each hole must be at least 0.2 inches wide and cannot be closer than 0.2 inch from the outside edge of the shield or guard. These holes allow a child to continue breathing even if the child sucks the pacifier guard into his or her mouth.

¹ This document is a general summary of the pacifier requirement and does not replace or supercede the requirements published in 16 C.F.R. 1511. This summary does not include all of the details included in those requirements. Please refer to the regulation for those details.

What does the standard say about protrusions?

Parts cannot stick out more than 0.63 inches from the face of the guard or shield on the side opposite the nipple. To test for a protrusion, clamp the pacifier by its nipple so that it will not move. Place an object with flat surface, such as a piece of wood or hard plastic, directly on any handle, ring, or other part that protrudes from the shield or guard on the other side of the nipple. Gradually push the object toward the nipple, allowing the protrusion you are testing to bend or, if it is a hinged handle or ring, to move. Make sure that you apply the force in the direction that follows the length of the nipple. Once you reach a force of two pounds, measure the distance between guard or shield and the surface of the test object.

Are there other requirements for pacifier strength?

Yes. There is a pull test. The pacifier must not come apart if you hold the handle or guard and gradually pull on the nipple in any possible direction for 5 seconds until you reach 10 pounds. Hold that force for 10 more

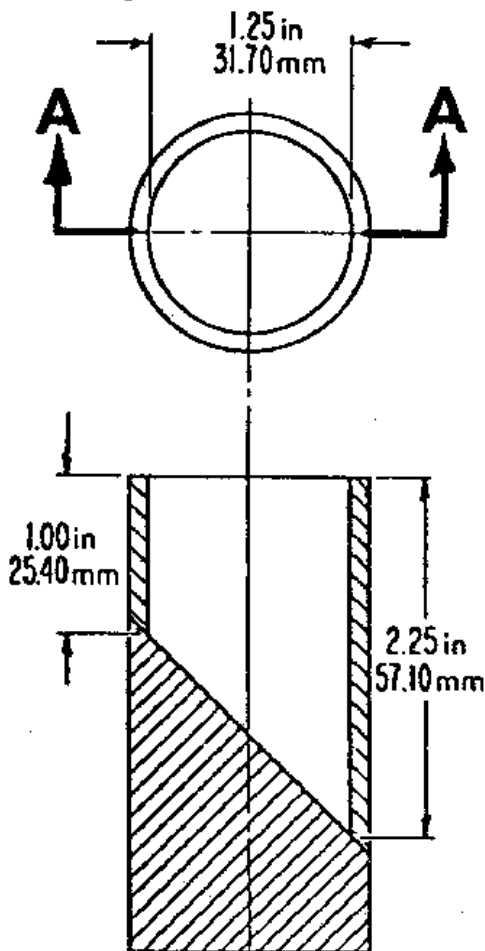


Figure 2 - Small Parts Test Cylinder

seconds. The handle or ring must pass the same test. Both the nipple and the handle or ring must also pass these same tests after the pacifier has been boiled and cooled six times. Boiling the pacifier simulates how parents sterilize pacifiers in the home.

If any pieces come off during the pull tests, test the parts to see if they fit entirely into the "small parts" test cylinder (Figure 2). The cylinder approximates the size of a child's throat. If any part fits, the pacifier is banned because a child could choke on the part.

Are there any other requirements for pacifiers?

Yes. To prevent a child from strangling, a pacifier cannot be sold or distributed with any ribbon, string, cord, chain, twine, leather, yarn or similar attachment. In addition, pacifier packages must be clearly labeled on the front "Warning- Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger."

Does CPSC have any other requirements that apply to pacifiers?

Yes. Pacifiers may not have sharp points or edges or be painted with paint that contains more than 0.06% lead. (See 16 C.F.R. 1500.48, 16 C.F.R. 1500.49, and 16 C.F.R. 1303)

Are there any standards for chemical hazards?

The Commission has no mandatory standards addressing chemical hazards. ASTM F963, the Standard Consumer Safety Specification on Toy Safety, Pacifiers, Section 4.22 addresses cancer risks in rubber nipples by providing that these nipples shall not contain more than 20 ppb. total nitrosamines. See ASTM F1313 for more detail on nitrosamine testing.

Where can I find additional Information?

You can obtain the Requirements for Pacifiers, 16 C.F.R. Part 1511, from the Commission's Web Site at: <http://www.cpsc.gov>. For more information on the requirements for pacifiers contact the Consumer Product Safety Commission, Office of Compliance, Washington, D.C. 20207, telephone: (301) 504-7913, e-mail: sect15@cpsc.gov.

For copies of the Standard Consumer Safety Specification on Toy Safety (ASTM F 963) and Volatile n-Nitrosamine Levels in Rubber Nipples on Pacifiers (ASTM F1313) contact the American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, telephone: (610)-832-9585, Fax (610)-832-9555, or visit <http://www.astm.org>.