

ENGINEERING TEST MANUAL  
REQUIREMENTS FOR PACIFIERS

16 CFR PART 1511

ES DOC 540732

Engineering Sciences  
Engineering Laboratory

5 "This engineering test manual has been developed to provide guidance to Commission staff members who test pacifiers for compliance with CPSC Pacifier Regulations 16 CFR PART 1511. The test manual is not intended to supercede or limit the Pacifier Regulation. In the case of discrepancy between the regulation and this test manual, the regulation will supercede the test manual."

September 1984

CONSUMER PRODUCT SAFETY COMMISSION  
WASHINGTON, D.C.

## TABLE OF CONTENTS

	Page
I. Background	1
II. Scope	1
III. Applicable Documents	1
IV. General Procedures	2
A. Safety Precautions	2
B. Equipment Calibration and Accuracy	2
C. Equipment	2
1. General Equipment	2
2. Specified Equipment	4
D. Sample Identification	4
E. Test Flow	4
F. Sample Submissions Required	4
G. Data Acquisition and Report Format	5
H. Laboratory Environment	5
I. Personnel and Test Report Certification	5
V. Test Criteria and Procedures	6
A. Visual Tests	6
B. Mechanical Tests	6
1. Guard or Shield	6
2. Ventilation Holes	7
3. Protrusion Test	8
4. Structural Integrity	9
a. Requirement	9
b. Nipple Test Procedure	10
c. Handle or Ring Test Procedure	11
d. Heat Cycle Deterioration Test Procedure	12
VI. Figures	13
VII. Requirements for CPSC Test Report for Pacifiers	18
Appendix	
A. CPSC Test Report for Pacifiers ES-DOC 540750	20
B. 16 CFR Part 1511 Requirements for Pacifiers	24

## I. BACKGROUND

The Consumer Product Safety Commission (CPSC) promulgated a safety regulation for pacifiers with an effective date of February 26, 1978. The regulation provides performance criteria and test procedures, but may not provide specific details of how each test is to be conducted and reported. In order to provide a uniform system of testing and reporting within the CPSC, this detailed Engineering Test Manual has been developed. Additional guidelines, with regard to potential problems which might be encountered in performing the compliance tests, have also been incorporated into this document.

## II. SCOPE

This Engineering Test Manual sets forth the detailed test procedures, test equipment, test flow, report format and test personnel certification to be utilized within the Commission in the compliance testing of pacifiers. The details prescribed in this document set forth the method the CPSC will use.

## III. APPLICABLE DOCUMENTS

A. Pacifier Regulation 16 CFR Part 1511 (See Appendix).

#### IV. GENERAL PROCEDURES

##### A. Safety Precautions

(1) The Test Engineer shall be responsible for the safety, competence and training of all testing personnel. All tests shall be conducted in such a manner as to provide the maximum protection to those individuals conducting the tests.

(2) Special care should be exercised in handling the heating equipment, the boiling water, and the pacifiers used during the heat cycle deterioration tests.

B. Equipment Calibration and Accuracy. All equipment used in the performance of the tests shall be maintained in conformance with the headquarters Laboratory Calibration and Maintenance Program. The selection of specific equipment to be used for each test shall be the responsibility of the Test Engineer but in all cases the equipment utilized will provide the accuracy and precision necessary to withstand the scrutiny of possible legal actions.

C. Equipment. The following list prescribes the general equipment to be used in the performance of the tests as well as any equipment or apparatus specified in the Standard:

##### 1. General Equipment

- a. Spring force gage capable of applying tensile or compressive force up to 10 pounds and measuring force accurate to at least 0.1 pound.
- b. Compression disc, 1.5 inch diameter, to be attached to spring force gage.
- c. Vessel to contain boiling water to perform heat cycle deterioration tests.
- d. Metal screen to hold pacifiers completely submerged in boiling water.
- e. Timer to indicate elapsed time and accurate to at least one second.
- f. Universal vernier or dial caliper capable of measuring inside or outside dimensions accurate to at least 0.001 inch.
- g. Inside spring caliper.
- h. Assorted clamps.
- i. Ventilation hole gage\* (see Figure 1).
- j. Mass with clamp\* having a total weight of 2 (+0 - 0.02) pounds (see Figure 2).

\*To be supplied by Headquarters Engineering Laboratory.

## 2. Specified Equipment

a. Pacifier Test Fixture\* (see Figure 3).

b. Small Parts Gage\* (see Figure 4).

D. Sample Identification. A "sample" includes all items received under one sample number and may consist of several subs (items). Upon receipt of a sample, each sub shall be permanently marked so that the identification will remain throughout the tests. Such markings shall not affect the results of tests.

E. Test Flow. The tests shall be performed in the same order as they appear in this manual.

F. Sample Submissions Required. A sample shall consist of at least 24 subs. Subs 1 through 6 shall be subjected to the tests indicated on Table 1. Subs 7 through 24 shall be reserved for additional testing if necessary or shall remain in an untested condition. If a pacifier fails to meet one or more of the test requirements, additional testing to the requirements not met shall be performed on four more subs.

\*To be supplied by Headquarters Engineering Laboratory.

Table 1: Sample Subs and Tests to be Performed

<u>Sub Number</u>	<u>Name of Test</u>	<u>Reference Paragraph Test Manual/Fed. Reg.</u>	
1 through 6	Visual Test	V.A.1.	1511.6
		V.A.2.	1511.7
1, 2, 3	Guard or Shield	V.B.1.	1511.3(a)
	Ventilation Holes	V.B.2.	1511.3(b)
	Structural Integrity	V.B.4.	1511.5
4, 5, 6	Protrusion Test	V.B.3.	1511.4

G. Data Acquisition and Report Format. The CPSC Test Report for Pacifiers (see Appendix) shall be used for all reporting of results. A copy of all field laboratory test reports and any data acquisition forms shall be sent to the Headquarters Engineering Laboratory.

H. Laboratory Environment. All tests shall be conducted in ambient laboratory conditions of between 15° to 27°C (60° to 80°F) unless otherwise specified in the Standard.

I. Personnel and Test Report Certification. All reports shall be prepared on the form specified herein and shall be certified as to the accuracy and conformance to all the requirements of this Test Manual by the Test Engineer. The Test Engineer shall be a suitable trained expert and certified by the Director of the CPSC Headquarters Engineering Laboratory. Prior to tests, the Test Engineer shall insure that all test operators are familiar with the procedures of this manual.

## V. TEST CRITERIA AND PROCEDURES

A. Visual Tests. Samples shall be visually inspected according to the following requirements and violations shall be noted in Part A of the Pacifier Test Report (see Section VI.).

1. A pacifier shall not be sold or distributed with any ribbon, string, cord, chain, twine, leather, yarn, or similar attachment.

2. Pacifiers shall be labeled "Warning - Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger". The label shall appear legibly and conspicuously on any retail display carton containing two or more pacifiers. Note in the test report whether the label has the required warning statement and the location of the label on the shelf package or box. Each individually packaged pacifier shall also bear the labeling statement on the package legibly and conspicuously. Again, note in the test report whether the label has the required warning statement and the location of the label on the shelf package or box.

B. Mechanical Tests. The following tests shall be performed as described and test results shall be noted in Part B of the Pacifier Test Report.

### 1. Guard or Shield

a. Requirement: A pacifier guard or shield shall not be drawn completely through the opening in the Pacifier Test Fixture (see Figure 3) when a tensile force, applied to the nipple, is increased gradually to a force not exceeding two pounds in a period of five seconds and is maintained

3Revised 9/11/84



at two pounds for an additional 10 seconds.

b. Procedure: Clamp the pacifier test fixture in a horizontal plane such that the radiused lip of the opening is facing upwards. Place the pacifier, with the nipple facing downwards, over the opening and center the nipple axis on the axis of the opening. Attach the weight to the nipple, using a suitable clamp, such that the mass of the clamp plus the weight is as close to, but does not exceed, two pounds. Gradually allow the suspended mass to exert a vertical force to the nipple within a five second period and allow it to remain freely suspended for an additional 10 seconds. Record the pass or fail on the Test Report Form. Some types of pacifiers which have irregular shaped shields require additional care to prevent the complete pacifier from moving horizontally off the axis of the opening.

## 2. Ventilation Holes

a. Requirement: The pacifier guard or shield shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier guard or shield.

b. Procedure: Using the plug gage shown in Figure 1 of this manual, check the compliance of the minor dimension of at least two holes. The gage shall be capable of being freely inserted into the holes. If the plug gage cannot be freely inserted into the holes, measure the diameter of the holes using the universal caliper. Record the failing hole diameter dimensions.

Use the universal caliper to determine that the dimension of the nearest edge of each of two holes to the perimeter of the shield is not less than 0.20 inch. Record the dimension on the Test Report Form.

If the shield is manufactured from a resilient material (i.e. latex rubber), care shall be exercised to avoid distorting the material and obtaining a smaller, false measurement, for this dimension.

### 3. Protrusion Test

a. Requirement: No protrusion from the face of the guard or shield opposite the nipple shall exceed 0.63 inches when measured in accordance with the following procedure.

b. Procedure: Secure the pacifier, with its axis horizontal, by a clamp attached to the nipple as close to the shield as is possible. Any hinged handle or ring shall have its hinge axis horizontal and shall be allowed to rotate under the influence of its own weight.

Attach a 1.5 inch diameter disk with a plane face to the force gage so that the axis of the force gage passes through the center of the disk and the plane face is normal to this axis (see Figure 5). Align the axis of the force gage with that of the pacifier and move the plane face of the disk towards the protrusion on the pacifier. Allow any flexible component to buckle or bend and continue the motion towards the shield until the force gage indicates a force of 2.0 pounds. A pacifier which has a ring, handle or other protrusion which is fabricated from a nonrigid material, but which does not deflect under the influence of its own weight, may be manually deflected as the plane face is brought towards it, if by doing so, the force which it exerts on the plane face is reduced.

While maintaining the two pound force, measure the distance using the inside spring caliper from the plane face of the disk to the face of the shield at the base of the nipple as illustrated by Figure 5. Record this measurement on the Test Report Form.

#### 4. Structural Integrity

a. Requirement: Any components or fragments which are released as a result of the Nipple Tests or the Handle or Ring Tests shall be placed in the Small Parts Gage shown in Figure 4, such that the component or

fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

b. Nipple Test Procedure: Hold the pacifier firmly by attaching clamps to the guard or shield in a manner which will not influence the structural integrity of the pacifier. The orientation of the pacifier may be in any convenient direction. Grasp the nipple with a suitable clamp attached to the force gage. Gradually apply a tensile force in the direction of the nipple axis such that the force reaches, but does not exceed 10 pounds in five seconds. Maintain this force for an additional 10 seconds or until the nipple or a component of the pacifier separates.

3           <sup>3</sup>If no separation occurs, the CPSC Test Engineer shall repeat this test with a different sub, applying the force at an angle to the nipple axis. The angle may be up to 90°, based upon the CPSC Test Engineer's judgment as to what the angle is most likely to result in separation. The CPSC Test Engineer's judgment shall be based upon the configuration, material and/or design of the pacifier. The approximate angle and the reason(s) for the angle selected shall be noted on the Comment section of the test report. No more than one nipple test before and one nipple test after the Heat Cycle shall be performed on any one sub.

If on any pacifier a separation of the nipple occurs, place any separated component into Small Parts Gage in accordance with the requirement of this section. Record pass or fail test result on the Test Report Form.

c. Handle or Ring Test Procedure: Use the same submissions as were used in the Nipple Test. Hold the pacifier firmly by attaching clamps to the guard or shield or base of the nipple. Grasp the handle, ring or other protrusion, located on the side of the shield opposite the nipple, with a suitable clamp attached to the force gage. Gradually apply a tensile force in the direction of the nipple axis such that the force reaches, but does not exceed 10 pounds in five seconds. Maintain this force for an additional 10 seconds or until the handle or ring or a component of the pacifier separates. <sup>3</sup>If no separation occurs, the CPSC Test Engineer shall repeat this test with a different sub, applying the force at an angle to the nipple axis. The angle may be up to 90°, based upon the CPSC Test Engineer's judgment as to what angle is most likely to result in separation. The CPSC Test Engineer's judgment shall be based upon the configuration material and/or design of the pacifier. The approximate angle and the reason(s) for the angle selected shall be noted on the Test Report Form. No more than one handle or ring test before and one handle or ring test after the Heat Cycle shall be performed on any one sub.

If on any pacifier a separation of a handle or ring occurs, place any separated component into the Small Parts Gage in accordance with the requirement of this section. Record pass or fail test result on the Test Report Form. If separation occurs and parts pass the small parts requirement, retest with another submission by clamping at the base of the nipple (nipple side of shield) and repeat the loading on the handle as indicated above.

3           <sup>3</sup>NOTE: The order in which the Nipple Test and the Handle or Ring Test are performed shall be based upon the CPSC Test Engineer's judgment as to which sequence is more likely to result in a failure. The CPSC Test Engineer's judgment shall be based upon the configuration, material and/or design of the pacifier. For example, if after examination of the pacifier, the CPSC Test Engineer believes that a failure is more likely to occur if the 10 pound force is applied to a handle, to a ring or to some other protrusion before the force is applied to the nipple, the test shall be reversed in order. The order of testing and the CPSC Test Engineer's reason(s) for the testing sequence shall be noted in the Comment section of the test report.

          d. Heat Cycle Deterioration Test Procedure: After performing the Nipple Test and the Handle or Ring Test, place the pacifiers in a mesh basket or other suitable container which will facilitate submersion and removal from boiling water. Submerge the pacifiers in boiling water and start the timer. After five minutes of submersion, remove the pacifiers and place on a clean surface for a five minute cooling period in room temperature air at 60°-80°F. Perform a total of six boiling/cooling cycles. After the final (6th) boiling cycle, allow the pacifiers to cool in room temperature air for at least 20 minutes. The pacifiers shall be again subjected to the Structural Integrity Tests. The Nipple Test and the Handle or Ring Test may again be performed in any order at the discretion of the CPSC Test Engineer as noted above. <sup>3</sup>The order of testing and the reason(s) for the testing sequence selected should be noted in the Comment section of the test report. Next, the Guard or Shield Tests (V.B.1a. & b.) and the Ventilation Hole Tests (V.B.2.) shall be performed. All these tests shall be performed within one hour after the sixth boiling cycle.

Results of the testing after the Heat Cycle shall be recorded as "Meets Criteria (Yes/No)" on the report form.

<sup>3</sup>Revised effective 9/11/84

## VI. FIGURES

FIG 1—PLUG GAGE FOR  
PACIFIER GUARD (SHIELD)  
VENTILATION HOLE  
REQUIREMENT

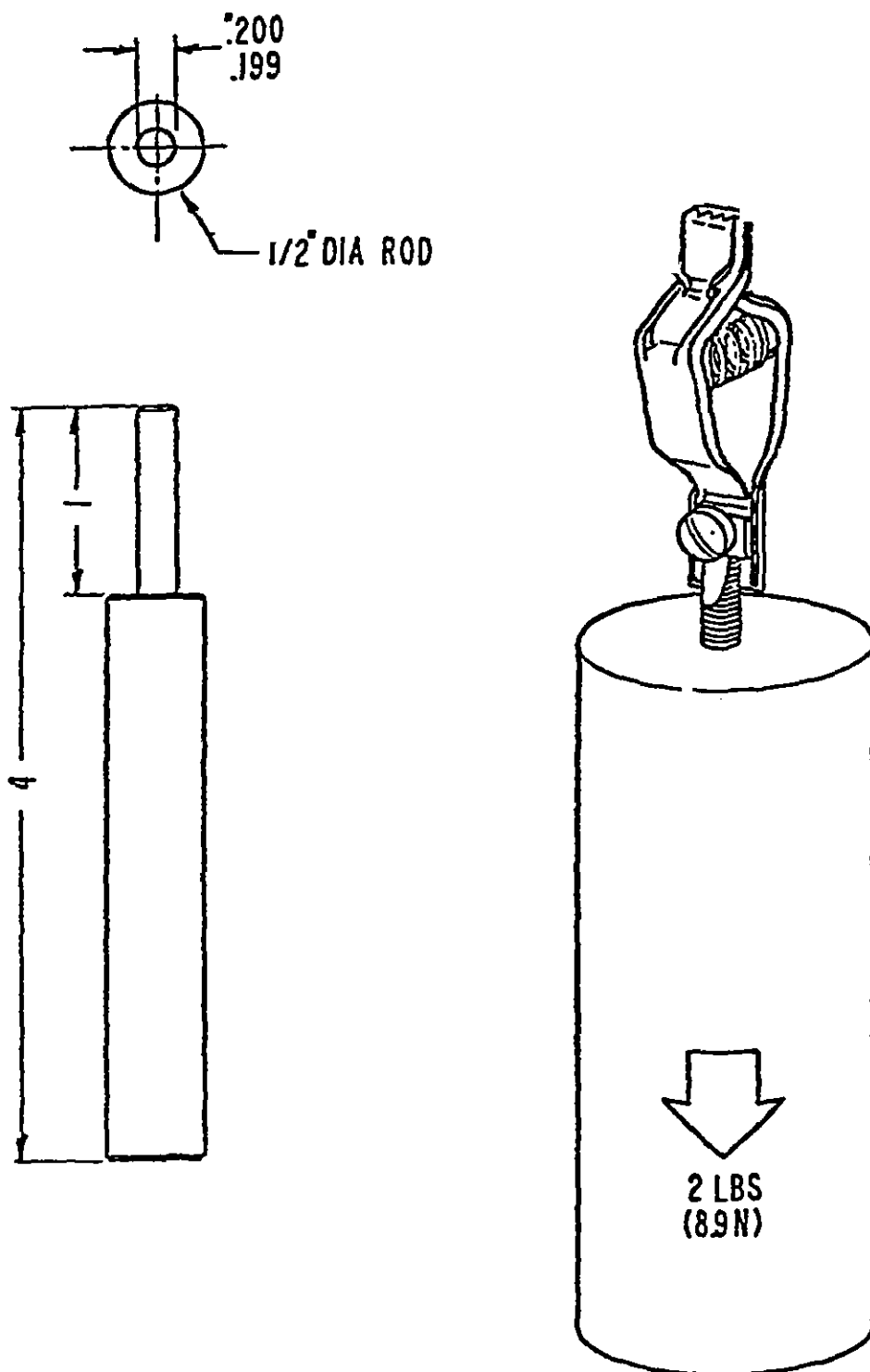


FIG 2—WEIGHT WITH CLAMP



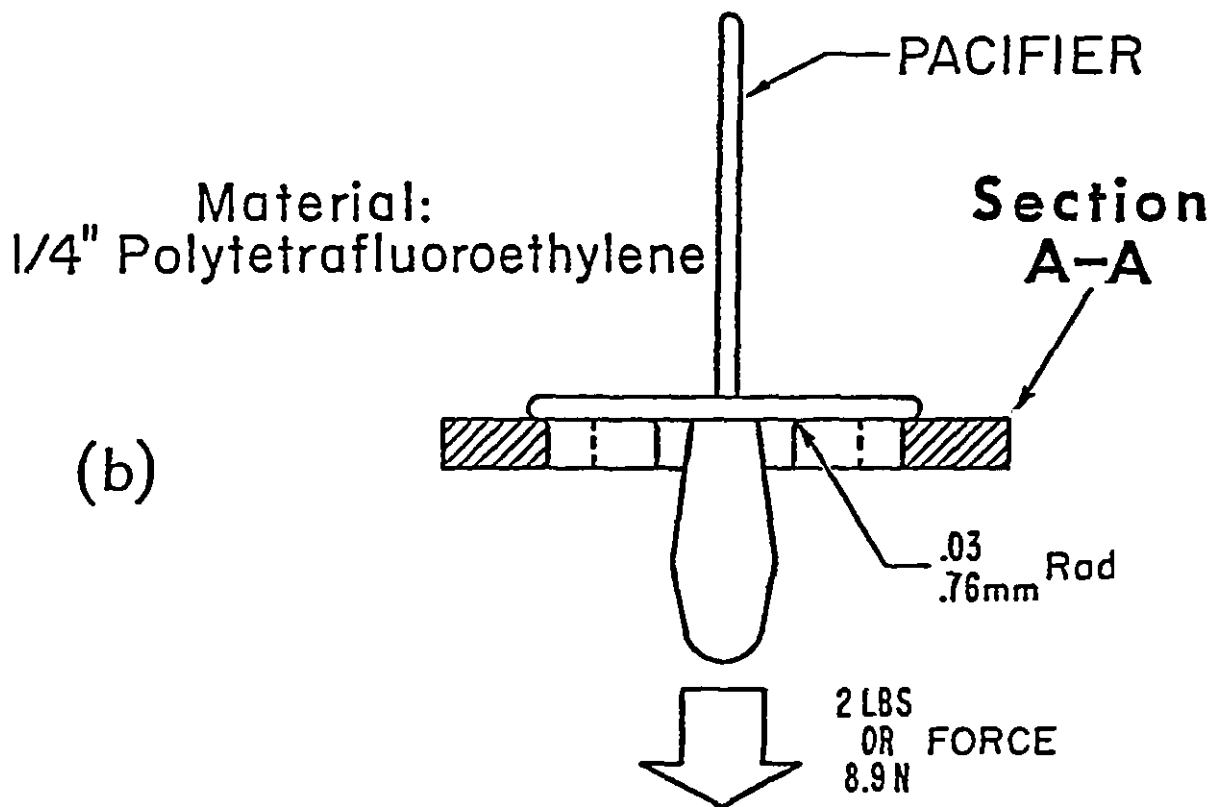
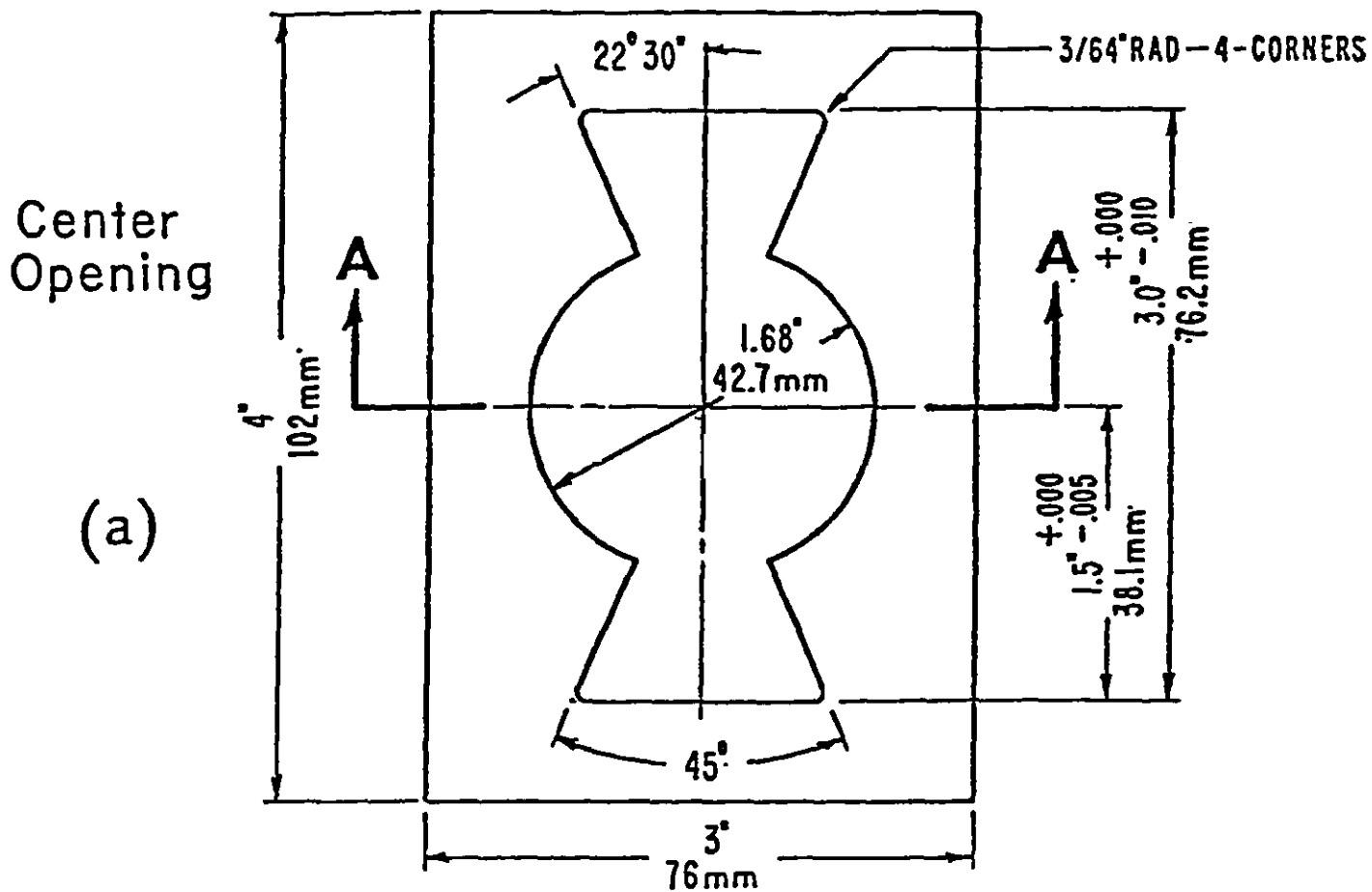
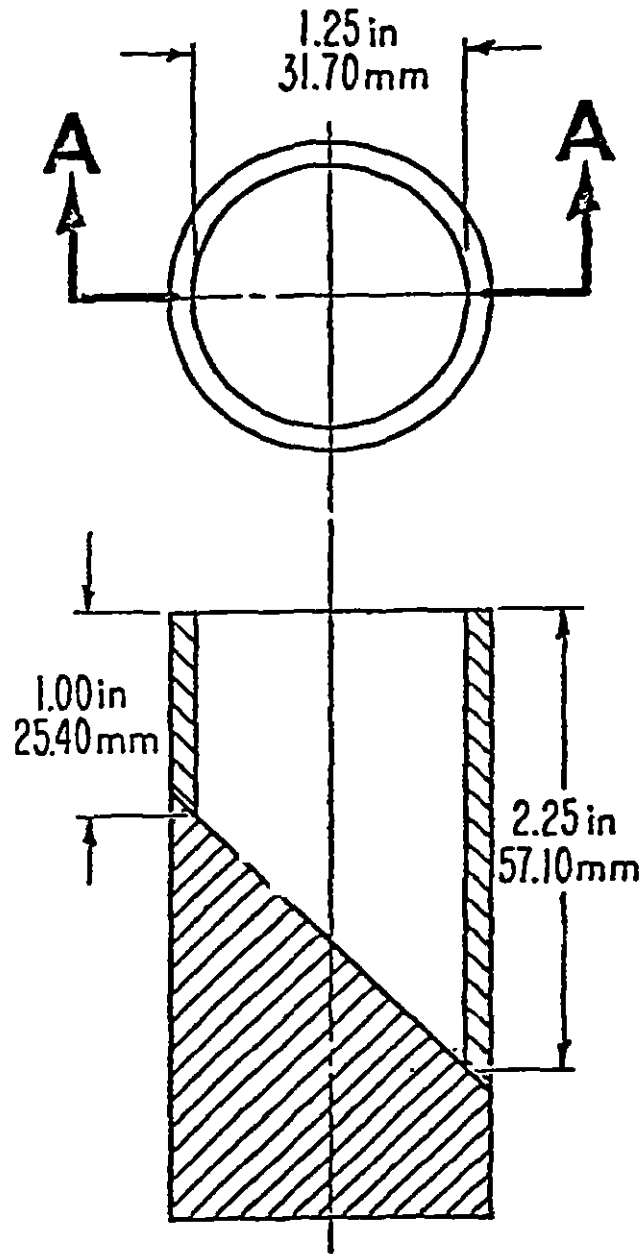


FIG 3- PACIFIER TEST FIXTURE



## Section A-A

FIG 4-SMALL PARTS GAGE

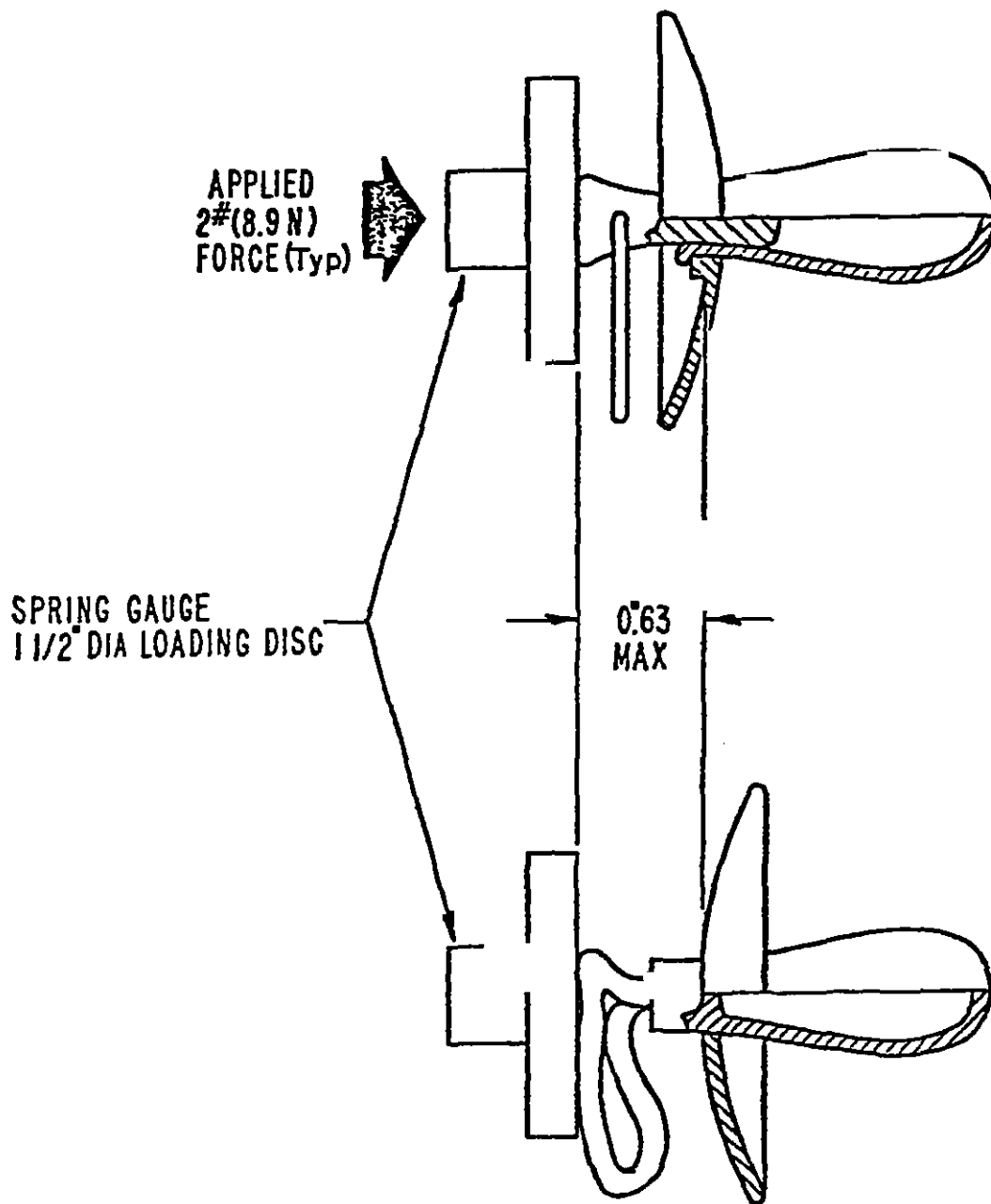


FIG 5—DIMENSIONAL REQUIREMENT  
IN PROTRUSION TEST

## VII. REQUIREMENTS FOR CPSC TEST REPORT FOR PACIFIERS

The Pacifier Report Form used to report the results shall be per Appendix A. The names of the test personnel involved shall be inserted and final approval and responsibility shall rest with an Engineering Science certified Test Engineer. All test conductors or analysts shall be approved by the certified test engineer.

## CPSC TEST REPORT FOR PACIFIERS

DATE(S) TESTED: \_\_\_\_\_

SEAL: INTACT \_\_\_\_\_ BROKEN \_\_\_\_\_

MANUFACTURER OR IMPORTER: \_\_\_\_\_

SAMPLE NO: \_\_\_\_\_ COLLECTION REPORT: \_\_\_\_\_

MODEL OR STYLE NO: \_\_\_\_\_

MODEL NAME: \_\_\_\_\_

## APPROVAL RECORD

\_\_\_\_\_  
Test Analyst\_\_\_\_\_  
Date\_\_\_\_\_  
Supervisory Mechanical Engineer\_\_\_\_\_  
Date

CPSC TEST REPORT FOR PACIFIERS  
PART A: VISUAL TESTS  
Sample Number: \_\_\_\_\_

REFERENCE PARAGRAPH		OBSERVATIONS	OBSERVATION	
TEST MANUAL	REGULATION		SUB 1	SUB THROUGH
V.A.1.	1511.6	Pacifier has attached ribbon string, cord, etc. Record length of ribbon and describe		
V.A.2.	1511.7	Meets criteria (Yes/No) Required label "Warning - Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger".		
	(a)	Above label on retail carton containing two or more pacifiers (Yes/No)		
	(b)	Above label on individually packaged pacifiers (Yes/No)		
		4* Note whether the label is on the front, back, or side.		

Comments:

Form #1 - ES DOC 540750

4\* Revised 9/11/84

**CPSC TEST REPORT FOR PACIFIERS**  
**PART B: MECHANICAL TESTS**  
 Sample Number: \_\_\_\_\_

REFERENCE PARAGRAPH		REQUIREMENT	OBSERVATION	
TEST MANUAL	REGULATION		SUB 1	SUB THROUGH
V.B.1	1511.3	Guard or Shield Tests		
	(a)	Performance requirements		
		Meets criteria (Yes/No)		
V.B.2	(b)	Ventilation holes		
		Meets criteria (Yes/No)		
		( $\geq 0.20"$ )		
		Vent Holes		
		No. of holes...		
		Size of holes...		
		Dist. from perimeter.		
V.B.3.	1511.4	Protrusion Test, Measured distance from test surface to shield under 2.0 lbf	SUB 4	THRU SUB
		Meets criteria (Yes/No)		
		( $< 0.63"$ )		
V.B.4.	1511.5	Structural Integrity Tests	SUB 1	THRU SUB
b.		Prior to heat cycle (1511.5c):		
	(a) & (d)	Nipple test produces no small parts...		
		Meets criteria (Yes/No)		
c.	(b) & (d)	Handle or ring test produces no small parts...		
		Meets criteria (Yes/No)		
d.	1511.5(c)	The following performed after Heat Cycle Deterioration Test:		
V.B.4.	1511.5	Nipple test produces no small parts...		
b.	(a) & (d)	Meets criteria (Yes/No)		
c.	(b) & (d)	Handle or Ring test produces no small parts...		
		Meets criteria (Yes/No)		
V.B.1.	1511.3(a)	Guard or Shield		
		Performance requirements...		
		Meets criteria (Yes/No)		
V.B.2.	1511.3(b)	4Ventilation Holes...		
		Meets criteria (Yes/No)		

Comments:

CPSC TEST REPORT FOR PACIFIERS  
PART C: EQUIPMENT USED FOR MEASUREMENT  
Sample Number: \_\_\_\_\_

NAME	MODEL	SERIAL NUMBER



## PART 1511—REQUIREMENTS FOR PACIFIERS

### Sec.

1511.1 Scope of Part 1511.

1511.2 Definitions.

1511.3 Guard or shield requirements.

1511.4 Protrusions.

1511.5 Structural integrity tests.

1511.6 Ribbons, strings, cords, or other attachments.

1511.7 Labeling.

1511.8 Metric references.

FIGURES 1—2

**Authority:** Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304-05, 83 Stat. 187-89; 15 U.S.C. 1261, 1262.

**Source:** 42 FR 32270, June 30, 1977, unless otherwise noted.

### § 1511.1 Scope of Part 1511.

This Part 1511 sets forth the requirements whereby pacifiers (as defined in § 1511.2(a)) are not banned articles under § 1500.18(a)(8) of this chapter.

### § 1511.2 Definitions.

(a) A "pacifier" is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid, and usually includes a guard or shield and a handle or ring.

(b) "Guard or shield" means the structure located at the base of the nipple used to prevent the pacifier from being completely drawn into the child's mouth.

(c) "Handle or ring" means the structure usually located adjacent to the guard or shield used for holding or grasping the pacifier. A hinged handle or ring is one that is free to pivot about an axis parallel to the plane of the guard or shield.

### § 1511.3 Guard or shield requirements.

(a) **Performance requirements.** Place the pacifier in the opening of the fixture illustrated in Figure 1(a) of this part so that the nipple of the pacifier is centered in the opening and protrudes through the back of the fixture as shown in Figure 1(b). For pacifiers with non-circular guards or shields, align the major axis of the guard or shield with the major axis of the opening in the fixture. Apply a tensile force to the pacifier nipple in the direction shown. The force shall be applied gradually attaining but not exceeding 2.0 pounds (8.9 newtons) within a period of 5 seconds and main-

10 seconds. Any pacifier which can be completely drawn through an opening with dimensions no greater than those of Figure 1(a) by such a force shall fail the test in this part.

(b) **Ventilation holes.** The pacifier guard or shield shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier guard or shield.

### § 1511.4 Protrusions.

(a) **Protrusions limitation.** No protrusion from the face of the guard or shield opposite from the nipple shall exceed 0.63 inches (16mm) when measured in accordance with the procedure specified in paragraph (b) of this section.

(b) **Protrusion test.** Secure the pacifier by clamping the nipple with its axis horizontal. For pacifiers with hinged handles or rings the orientation of the hinge axis shall be horizontal. A plane surface shall be applied to any protrusion from the guard or shield with a force gradually attaining but not exceeding 2.0 pounds (8.9 newtons) applied in a direction along the axis of the nipple. The normal of the plane surface shall be maintained parallel to the axis of the nipple. Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple.

### § 1511.5 Structural integrity tests.

(a) **Nipple.** Hold the pacifier by the shield or guard, grasp the nipple end of the pacifier and gradually apply a tensile force to the pacifier nipple in any possible direction. The force shall be applied gradually, attaining but not exceeding 10.0 pounds (44.5 newtons) within a period of 5 seconds and maintained at 10.0 pounds for an additional 10 seconds.

(b) **Handle or ring.** Hold the pacifier by the shield or guard or base of the nipple, and push or pull on the handle or ring in any possible direction. The force shall be applied gradually attaining but not exceeding 10.0 pounds (44.5 newtons) within a period of 5 seconds and maintained at 10.0 pounds

(c) **Heat cycle deterioration.** After the testing prescribed in paragraphs (a) and (b) of this section, all pacifiers shall be subject to the following: submerge the pacifier in boiling water for 5 minutes and then remove the pacifier and allow it to cool for 5 minutes in room temperature air, 60° to 80° F. (16° to 27° C). After the cooling period, re-submerge the pacifier in the boiling water for 5 minutes. The process shall be repeated for a total of 6 boiling/cooling cycles. After the sixth cycle, the pacifier shall again be subjected to the structural tests in paragraphs (a) and (b) of this section and section 1511.3.

(d) **Small parts.** Any components or fragments which are released as a result of the tests specified in paragraphs (a), (b) and (c) of this section shall be placed in the truncated cylinder shown in Figure 2, such that the component or fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

### § 1511.6 Ribbons, strings, cords, or other attachments.

A pacifier shall not be sold or distributed with any ribbon, string, cord, chain, twine, leather, yarn or similar attachments.

### § 1511.7 Labeling.

(a) As required by paragraphs (b) and (c) of this section, pacifiers shall be labeled with the statement: "Warning—Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger."

(b) The labeling statement required by paragraph (a) of this section shall appear legibly and conspicuously on any retail display carton containing two or more pacifiers.

(c) Each individually packaged pacifier shall bear the labeling statement required in paragraph (a) of this section on the package legibly and conspicuously.

### § 1511.8 Metric references.

For purposes of compliance with the test procedure prescribed by this § 1500.46, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

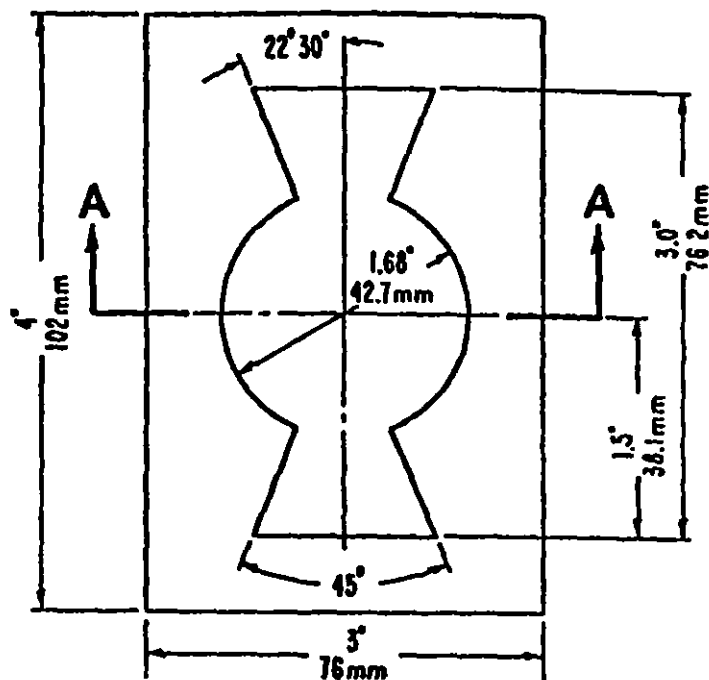
§ 1500.18 Banned toys and other banned articles intended for use by children.

(a) **Toys and other children's articles presenting mechanical hazards.** Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children present a mechanical hazard within the meaning of section 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

(8) Any pacifier that does not meet the requirements of 16 CFR Part 1511 and that is introduced into interstate commerce after February 26, 1978.

Center  
Cutout

(a)



Material:  
1/4" Polytetrafluoroethylene

Section  
A-A

(b)

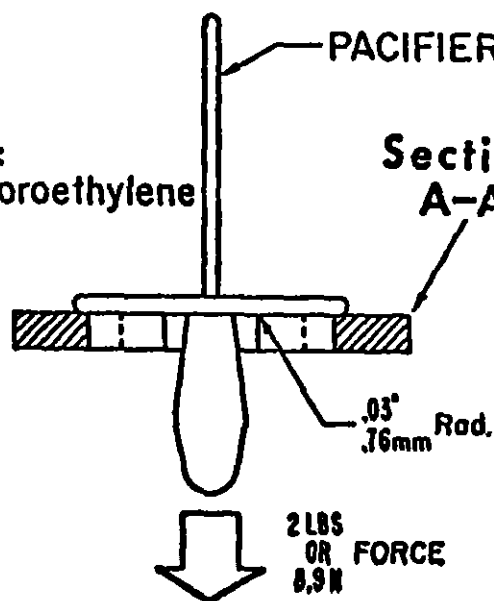
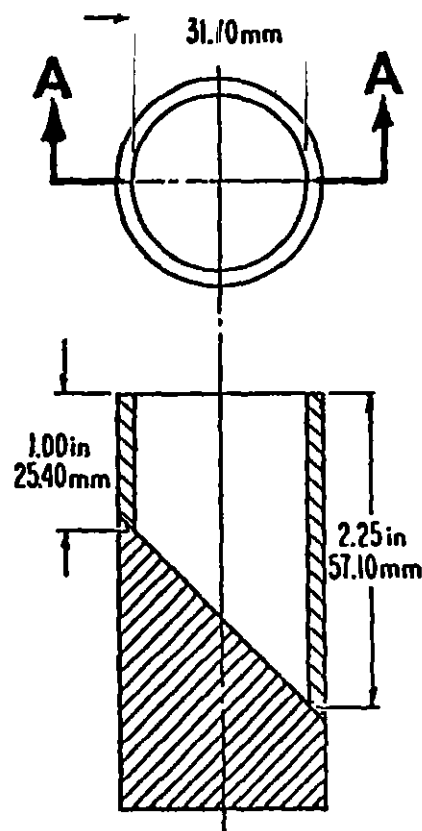


FIG 1-PACIFIER TEST FIXTURE



Section A-A

FIG 2-SMALL PARTS GAGE

Children's Pacifiers Containing  
Nitrosamines; Enforcement Policy

#### Statement of Policy

For the reasons explained above, the Commission has concluded, based on available information, that rubber pacifiers containing significant levels of nitrosamines are hazardous substances as defined in section 2(g) of the FHSA and thus are banned hazardous substances under section 2(q)(1)(A) of the FHSA because they are articles intended for use by children that bear or contain a hazardous substance in such a manner as to be susceptible of access to a child to whom the pacifier is given. Therefore, the Commission announces that it will bring enforcement cases against persons performing acts prohibited by section 4 of the FHSA in relation to rubber pacifiers that are

commerce after January 1, 1984, and that contain more than 60 parts per billion of nitrosamines as measured by methylene chloride extraction.<sup>1</sup> The Commission will test by the procedure used by FDA's National Center for Toxicological Research.<sup>2</sup> This announcement is to advise manufacturers and importers of rubber pacifiers that, without further notice in the Federal Register, the Commission will not initiate enforcement action so long as pacifiers initially introduced into interstate commerce after January 1, 1984, do not exceed 60 ppb by the method described above.

For more information on this Enforcement Policy see 48 FR 56988 (December 27, 1983)