

(TRANSLATION)
THAI INDUSTRIAL STANDARD
TIS 969-1990 (2533)

RUBBER NIPPLES FOR BABIES' BOTTLES

**Thai Industrial Standard
for
Rubber Nipples for Babies' Bottles**

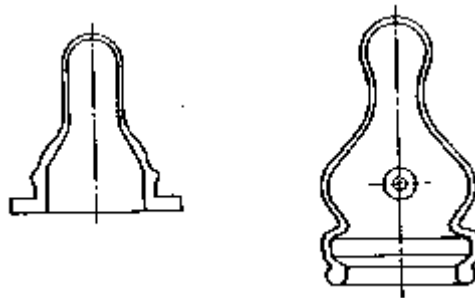
1. Scope

- 1.1 This standard specifies requirements, packaging, mark and label, sampling and criteria for conformity, and tests for rubber nipples for babies' bottles.
- 1.2 This standard does not cover rubber nipples to be used for nursing premature babies.

2. Definitions

For the purpose of this standard, the following definition shall apply.

- 2.1 RUBBER NIPPLE FOR BABY'S BOTTLE hereinafter referred to as "NIPPLE".
A product to be attached to a bottle for feeding to a baby nutritious liquids such as milk, potable water, liquid food, etc. Which is made from natural rubber, synthetic rubber or mixtures of thereof.
General shape of a nipple is as shown in Figure 1.



**Figure 1 General shape of nipple
(clause 2.1)**

3. Requirements

- 3.1 Appearance
- 3.1.1 Surface of a nipple shall be smooth and free from any imperfections such as tackiness, scrapes, strains, visible foreign matter in rubber, air bubbles, tears and smudges.
- 3.1.2 Nipple shall be free from any decorative colour.
Compliance is checked by visual inspection at a distance of 25 cm, or by contact with hands.
- 3.2 Workability
When tested by the method described in clause 7.2, the nipple shall not leak at the joint between the flange part and the bottle's cap.

- 3.3 Tensile load
When tested by the method described in clause 7.3, the nipple shall not tear.
- 3.4 Restoring performance
When tested by the method described in clause 7.4, the nipple shall not be deformed or cracked.
- 3.5 Boiling resistance
When tested by the method described in clause 7.5, the nipple shall show no sign of tackiness or cracking and the boiled water shall be clear, colourless and odourless. When subjected to the tests on tensile load and or restoring performance, the nipple shall satisfy the requirements of clauses 3.3 and 3.4, respectively.
- 3.6 Stability
When tested by the method described in clause 7.6, the nipple shall show no sign of tackiness or cracking and when subjected to the tests on tensile load and on restoring performance, it shall satisfy the requirements of clause 3.3 and 3.4 respectively.
- 3.7 Safety requirements
3.7.1 Safety requirements for rubber
Table 1 shall apply.

Table 1
Safety requirements for rubber
(clause 3.7.1)

Item	Element	Maximum element in mg/kg	Test ref. to
1	Lead	10	TIS 656
2	Cadmium	10	clause 7.7
3	Total nitrosamines	0.01	clause 7.8

Note. TIS 656 refers to Thai Industrial Standard for methods of analysis for plastics products used for food contact.

- 3.7.2 Safety requirements for chemical migrations
The concentration of element migration shall comply with Table 2.
Compliance is checked by the method described in clause 7.9

Table 2
Concentration of element migration
(clause 3.7.1 and 7.9.1)

Item	Element	Solvent	Maximum element in mg/dm ³ of solution
1	Phenol	Water	5
2	Formaldehyde	water	4
3	Zinc	Hydrochloric acid solution, 1+2	1
4	Residue on evaporation	Acetic acid solution, 4% v/v	40
		Water	40
5	Heavy metals (as lead)	Acetic acid solution, 4% v/v	1

4. Packaging

- 4.1 Nipples shall be packed in containers that can provide protection against damage and dirtiness which might occur during transportation and storage.

5. Mark and label

- 5.1 On the body of every nipple manufactured by the moulding process or on every nipple, there shall be at least number, letter or mark indicating clearly and legibly the following information.
- (1) Name of manufacturer or factory, or registered trademark
- 5.2 On every package unit of nipples, there shall be at least number, letter or mark indicating clearly and legibly the following information
- (1) Name of product
 - (2) Number of contents (if more than 1 nipple per package)
 - (3) Month and year of manufacturer, and batch number
 - (4) Materials used for manufacture
 - (5) Recommendations for use and storage
 - (6) Name of manufacturer or factory, or registered trademark, or distributors
- 5.3 In case foreign language is used, the meaning shall correspond to that in Thai specified above.
- 5.4 Any person who manufactures products complying with this standard, may use the Standards Mark in connection with his products only after having received a license from the Industrial Product Standards Council.

6. Sampling and criteria for conformity

- 6.1 Lot in this standard means nipples of the same shape and trademark made from the same material by the same process which are manufactured, delivered, or purchased at the same period of time.
- 6.2 Sampling and acceptance shall comply with the following plan or other technically equivalent plan.

- 6.2.1 Sampling and acceptance for tests on packaging, and mark and label on packages
 - 6.2.1.1 Samples shall be drawn at random from the same lot as given in column 2 of Table 3.
 - 6.2.1.2 Provided the number of samples failing to comply with each of the requirements of clauses 4 and 5.2 does not exceed the acceptance number specified in Table 3, that lot of nipples shall be deemed to comply with the requirements.
- 6.2.2 Sampling and acceptance for tests on appearance, and mark and label on nipples
 - 6.2.2.1 One sample from each package as in clause 6.2.1 shall be randomly drawn in accordance with column 3 of Table 3.
 - 6.2.2.2 Provided the number of samples failing to comply with each of the requirements of clauses 3.1 and 5.1 does not exceed the acceptance number specified in Table 3, that lot of nipples shall be deemed to comply with the requirements.

Table 3
Sampling plan for tests on packaging, mark and label on packages, appearance, and mark and label on nipples
(clauses 6.2.1 and 6.2.2)

Lot size packaging units	Sample size package units	Sample size units	Acceptance number
Up to 3000	2	2	0
3001 and over	8	8	1

- 6.2.3 Sampling and acceptance for tests on workability, tensile load, restoring performance, boiling resistance and stability
 - 6.2.3.1 Samples shall be drawn at random from the same lot as given in Table 4.
 - 6.2.3.2 Provided the number of samples failing to comply with each of the requirements of clauses 3.2, 3.3, 3.4, 3.5 and 3.6 does not exceed the acceptance number specified in Table 4, that lot of nipples shall be deemed to comply with the requirements.

Table 4
Sampling plan for tests on workability, tensile load, restoring performance, boiling resistance and stability
(clause 6.2.3)

Lot size units	Sample size units	Acceptance number
Up to 10000	3	0
10001 and over	13	1

- 6.2.4 Sampling and acceptance for tests on safety requirements for rubber
 - 6.2.4.1 Thirty samples shall be drawn at random from the same lot and cut into small pieces, each having a side area of about 5 mm², then mixed thoroughly and taken as a composite sample.

- 6.2.4.2 Provided the sample meets the requirements of clause 3.7.1, that lot of nipples shall be deemed to comply with the requirements.
- 6.2.5 Sampling and acceptance for tests on safety requirements for chemical migrations
 - 6.2.5.1 Twenty samples shall be drawn at random from the same lot and taken as a composite sample.
 - 6.2.5.2 Provided the sample meets the requirements of clause 3.7.2, that lot of nipples shall be deemed to comply with the requirements.
- 6.3 Criteria for conformity

If the sample meet all the requirements of clauses 6.2.1.2, 6.2.2.2, 6.2.3.2, 6.2.4.2 and 6.2.5.2, that lot of nipples shall be deemed to comply with this standard.

7. Tests

7.1 Test conditions

Keep the samples for at least 24 hours at $27^{\circ}\pm 2^{\circ}\text{C}$ and relative humidity of $65\pm 5\%$, then subject to test under the same condition.

7.2 Test on workability

Assemble a sample nipple on a baby's bottle of the corresponding dimensions which has been filled to its nominal capacity with water. Invert vertically the assembled baby's bottle, then shake up and down. Visually examine leakage at the joint between the bottle's cup and the flange of the sample nipple.

7.3 Test on tensile load

7.3.1 A tensile tester as shown in Figure 2, comprising

- 7.3.1.1 A fixed plate, and
- 7.3.1.2 A metallic mass with a hanger

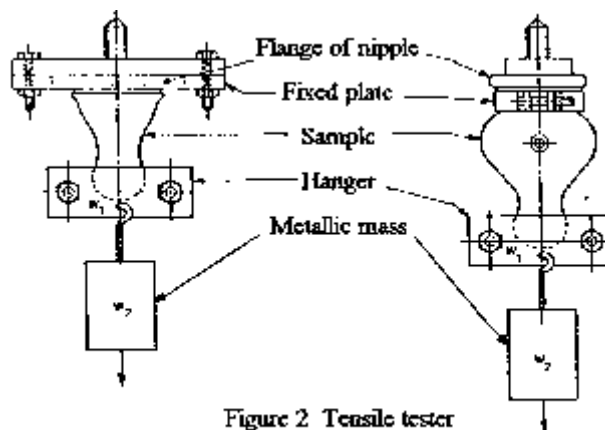


Figure 2 Tensile tester
(clauses 7.3.1 and 7.3.2.1)

7.3.2 Procedure

7.3.2.1 Arrange the tensile tester as shown in Figure 2, then

7.3.2.2 Hang a metallic mass for 3 minutes and

7.3.2.3 Examine the condition of the sample.

7.4 Test on restoring performance

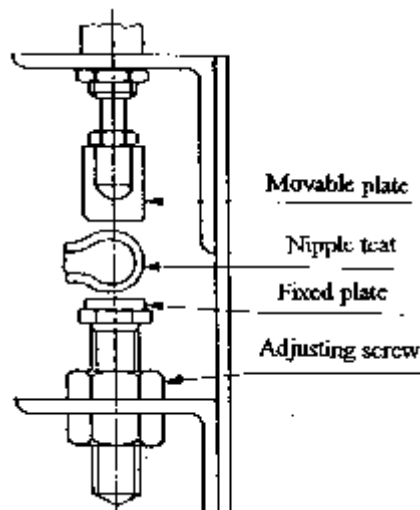
7.4.1 Apparatus

7.4.1.1 A compression tester as shown in Figure 3 shall consist of 2 metallic plates; the lower is a fixed plate and the upper is a vertically movable plate with an adjusting screw.

7.4.2 Procedure

7.4.2.1 Adjust the tester so that the distance between the movable plate and the fixed plate is not less than the outside diameter of the sample nipple, and that when full load is applied, the distance is equal to $1/2$ the outside diameter of the sample nipple.

7.4.2.2 Insert the teat of the sample nipple between the 2 plates of the compression tester and compress at a speed of 200-300 times/minute. After 2000 compression, the condition of the nipple teat shall be visually inspected.



**Figure 3 Compression tester
(clause 7.4.1.1)**

7.5 Test on boiling resistance

Boil the sample nipples for 3 hours in adequate quantity of distilled water, then remove and examine the sample nipples and the boiled water. Wipe off adhering water on the surfaces of the sample nipples, allow to cool at room temperature for 1 hour and subject to the tests on tensile load (clause 7.3) and on restoring performance (clause 7.4).

7.6 Test on stability

7.6.1 Apparatus

An electric oven capable of maintaining temperature at $70^{\circ}\pm 1^{\circ}\text{C}$.

7.6.2 Procedure

Condition the sample nipples for 72 hours in the oven maintained at $70^{\circ}\pm 1^{\circ}\text{C}$ avoiding contact with each other, or with the side, or floor of the oven. Allow to cool at room temperature for 1 hour, examine the condition of the sample and subject to the tests on tensile load (clause 7.3) and on restoring performance (clause 7.4).

7.7 Test on cadmium element

7.7.1 Chemicals, solutions and preparation

7.7.1.1 Nitric acid solution, 10% v/v

7.7.1.2 Nitric acid solution, 1 mol/dm^3

7.7.1.3 Concentrated sulfuric acid, relative density 1.84

7.7.1.4 Standard cadmium solution, 0.1 mg/dm^3

(1) Dissolve 10 mg of cadmium solution in 50 cm^3 of nitric acid solution (clause 7.7.1.1) and evaporate to dryness on a water bath. Dissolve the residue on evaporation in nitric acid solution (clause 7.7.1.2) in a 1000 cm^3 flask and fill to mark with nitric acid solution (clause 7.7.1.2)

(2) Pipette 1 cm^3 of the solution as in sub-clause (1) into a 100 cm^3 flask and dilute to mark with nitric acid solution (clause 7.7.1.2).

7.7.2 Preparation of sample solution

TIS 656 shall apply.

7.7.3 Procedure

The analysis shall be in accordance with TIS 656. After discarding the blank value, the absorption index of the sample solution shall not be more than that of the standard cadmium solution, for that sample to be deemed to have cadmium element not exceeding 10 mg/kg .

7.8 Test on total nitrosamines

7.8.1 Apparatus

7.8.1.1 A soxhlet extractor with a sintered -glass thimble

7.8.1.2 A Kuderna-Danish evaporator concentrator with a 250 cm^3 round-bottomed flask, or other appropriate size with stopper.

7.8.1.3 A thermostatic electric furnace

7.8.1.4 Gas chromatograph with the following conditions:

(1) A coiled glass column of 4 mm inside diameter and 2.7 mm long was packed with 10% of Carbowax 1540 plus 5% of potassium hydroxide on a $125\text{-}150\text{ }\mu\text{m}$ Chromosorb W (100-120 mesh), or equivalent.

- (2) A column, temperature programmed from 1000°-180°C at 4°C per minute.
- (3) An injection port maintained at 200°C
- (4) Argon carrier gas with flow rate of 40 cm³ /minute
- (5) A thermal energy analyzer operated by using interface at 250°C, pyrolyzer at 500°C, and 1 mm of oxygen pressure.
- (6) An analytical results recorder

7.8.2 Chemicals, solution and preparation

- 7.8.2.1 Di-chloromethane redistilled in a glass distillation apparatus and collected distilled at 40°C.
- 7.8.2.2 Sodium hydroxide solution , 5 mol/dm³
- 7.8.2.3 Anhydrous sodium carbonate
- 7.8.2.4 Anhydrous sodium sulfate
- 7.8.2.5 Carborundum grains
- 7.8.2.6 Distilled water after 2 distillations
- 7.8.2.7 Standard N-nitrosodimethylamine solution in aldehyde-free alcohol, 0.1 g/dm³
- 7.8.2.8 Standard N-nitrosodiethylamine solution in aldehyde-free alcohol, 0.1 g/dm³
- 7.8.2.9 Standard N-nitrosodibutylamine solution in aldehyde-free alcohol, 0.1 g/dm³
- 7.8.2.10 Standard N-nitrosopiperidine solution in aldehyde-free alcohol, 0.1 g/dm³
- 7.8.2.11 Standard N-nitrosopiperidine solution in aldehyde-free alcohol, 0.1 g/dm³
- 7.8.2.12 Standard mixed solution
Pipette equal portion of each of the standard solutions of clauses 7.8.2.7-8.2.11, then add aldehyde-free alcohol to a concentration of 0.1 mg/dm³.

7.8.3 Preparation of sample solutions

Weight approximately 5 g of the samples to an accuracy of 0.001 g into a 250 dm³ round-bottomed flask, add 100 cm³ of di-chloromethane and stopper. Let stand for 17-18 hours at room temperature. Connect a 250 cm³ round-bottomed flask containing boiling chips to a soxhlet extractor. Filter the di-chloromethane extract and the sample through a coarse sintered-glass so that the sample remains on the thimble and the di-chloromethane extract in the flask. Rinse the extraction flask 2 times, each with 12 cm³ of di-chloromethane. Add the rinse in the di-chloromethane extract in the round-bottomed flask. Place the thimble in the soxhlet extractor, distill the sample on an electric furnace adjusted so that the solution boils for 1 hour. Remove the soxhlet extractor and the round-bottomed flask from the electric furnace, let stand to cool to near room temperature. Then remove the soxhlet extractor into the round-bottomed flask, then add 100 cm³ of sodium hydroxide solution and boiling chips, distilled at 40°C and discard the di-chloromethane obtained at this distillation. Further distill the aqueous phase at about 100°C and collect 70 cm³ of that in a 250 cm³ separating funnel. To the distillate shall be added 300 mg of anhydrous sodium carbonate and the

distillate shall be extracted 3 times with 50 cm³ of di-chloromethane. The pooled extracts were dried by passing through 30 g of anhydrous sodium sulfate, held in a coarse sintered-glass filtering funnel, into a Kuderna-Danish evaporator concentrator. Add carborundum grains, evaporate to 4 cm³ at a rate of 1 cm³/minute in a 60°C water bath. Then remove from the Kuderna-Danish evaporator concentrator, allow to cool to near room temperature and further concentrate to 1 cm³ under a gentle stream of nitrogen.

7.8.4 Procedure

7.8.4.1 Inject 0.005 cm³ of standard mixed solution into a gas chromatograph, then note the time when peaks occur and calculate each peak area.

7.8.4.2 Inject 0.005 cm³ of the sample solution by taking the di-chloromethane as a blank into a gas chromatograph, then note the time when peaks occur and calculate each peak area.

7.8.5 Calculation

Determine the concentration of total nitrosamines in the sample solution by comparing the total area of the sample solution to that of the standard mixed solution, then calculate the total nitrosamines concentration of the sample solution in mg/kg.

7.9 Test on safety requirements for chemical migrations

7.9.1 Preparation of sample solution

Weight each piece of the sample nipples to an accuracy of 0.001 g, then extract by the method specified in TIS 656 using 2 cm³ of the solvents given in Table 2 per 0.1 g of the sample.

7.9.2 Procedure

7.9.2.1 Phenol, formaldehyde, residue on evaporation and heavy metals (as lead)

The analysis shall be in accordance with TIS 656.

7.9.2.2 Zinc

The analysis shall be in accordance with ISO 6101/1.