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Rubber teat (nipple) for baby feeding bottle — Specification

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The Executive Director
Uganda National Bureau of Standards
P.O. Box 6329
Kampala
Uganda
Tel: +256 414 333 250/1/2/3
Fax: +256 414 286 123
E-mail: info@unbs.go.ug
Web: www.unbs.go.ug

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Foreword

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The committee responsible for this document is Technical Committee UNBS/TC 303, *Plastics and related products*

Rubber teat (nipple) for baby feeding bottle — Specification

1 Scope

This Draft Uganda Standard specifies requirements, sampling and test methods for rubber teat (nipple) for baby feeding bottle

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
baby feeding bottle
bottle fitted with a nipple/ teat for feeding babies

3.2
teat (nipple)
rubber mouth-piece of a baby feeding bottle resembling the tip of a mammary gland

3.3
extractable mater
organic and inorganic chemical species that can be released from the surface of the teat (nipple)

3.4
axis
the line between the center and the longitudinal point of the rubber teat

4 Requirements

4.1 General requirements

4.1.1 The teat shall be made from food grade rubber together with necessary compounding and vulcanizing ingredients. The teat shall be free from grits, reclaimed rubber or vulcanized waste.

4.1.2 All ingredients used shall be free from harmful substances liable to extraction by contact with liquid foods or which may cause the development of undesirable odour, taste or discolouration.

4.1.3 Softeners, organic accelerators and antioxidants, if incorporated, shall not impart an undesirable odour or taste to the finished rubber teats. The following accelerators are recommended:

a) Dithiocarbamates, and

b) Appropriate Derivatives of Mercaptobenzothiazole.

4.1.4 The teats shall be transparent or translucent and shall be free from patches, blisters, porosity, sticky abrasions, stains, spots burrs/ flash, embedded foreign matter or any other defects when examined visually.

4.1.5 The shape and size of the rubber teats shall be appropriate for use in feeding babies

4.2 Specific requirements

Rubber teat for baby feeding bottle shall conform to the specific requirements in Table 1

Table 1 – Specific requirements for rubber teat for baby feeding bottle

SN	Characteristic	Requirement	Test method
1	Extractable mater,%, max	3	Annex A
2	Free sulphur, %, max by weight	0.2	Annex B
3	Change in physical properties	No sign of deterioration such as tackiness, hardness, crackiness and discolouration	Annex C
4	Colour, odour and turbidity	No impacting colour, odour or turbidity	
5	pH	7.0 ± 0.5	Annex D
6	Percentage deformation under tension, %, max	20	Annex E
7	Tear resistance	No crack or tear	Annex F
8	Temperature	No crack or tear	Annex G
10	N-nitrosamines, mg/kg, max	0.01	Annex H
	N-nitrosatable, mg/kg, max	0.1	
11	Bottle adhesion	No crack or tear, no leakage	Annex I

5 Packaging

The rubber teat shall be packaged in suitable containers that guarantee product integrity during transportation, storage and handling.

6 Labelling

Each teat or package or both shall be legibly marked with the following:

a) name and physical address of manufacturer or trade-mark, if any;

b) name of product as, “bottle teats (nipples)”

c) type of rubber used

d) instruction for use, hygienic care, disposal and caution/warnings

e) number of teats in each package;

f) batch number and

g) month and year of manufacture.

7 Sampling

For the purpose of ascertaining the conformity of the rubber teats to this specification, the scale of sampling and criteria for conformity shall be as prescribed in Annex J.

Annex A
(normative)

Determination of Acetone extractable matter from rubber teats

A.1 Outline of the Method

A known quantity of the sample is weighed and wrapped in a filter paper, folded, so that the particles cannot become detached and find their way into the extraction flask. The sample is then placed in the siphon cup of the extraction apparatus and extracted for a period considered adequate for the separation involved by heating on a water bath. The extracted matter in the flask is freed from the solvent and its contents are dried at a constant temperature, cooled and weighed.

A.2 Procedure

A.2.1 Place a weighed specimen of approximately 2 g in a filter paper. If the specimen is in the form of a sheet, cut it with scissors into strips 3 to 5 mm in width. If the specimen may become tacky during extraction, take care that adjacent portions are separated by paper.

A.2.2 Fold the paper so that it will fit in the extraction cup and suspend the cup in a weighed extraction flask containing 50 to 75 ml 'of acetone. (Prior to weighing of the flask, it shall have been dried for 2 h at 70 ± 5°C and cooled in a desiccator to the temperature of the balance)

A.2.3 Extract the specimen continuously for 16 hours heating at such a rate that the time required to fill and empty the siphon cup will be between 2.5 and 3.5 minutes. Carefully note all characteristics of the extracts, both when hot and cold.

A.2.4 Evaporate off the acetone over a steam bath, using a gentle current of filtered air to prevent boiling. Remove the flask from the steam bath just prior to the disappearance of the last traces of solvent to prevent loss of extract.

A.2.5 Continue the passage of air through the flask for 10 minutes to remove the remaining solvent and dry the flask for 2 h at 70 ± 5°C in an air-bath. Cool in a desiccator to the temperature of the balance and weigh

A.3 Calculation

Calculate the percentage of the acetone extract as follows:

$$\text{Acetone extract} = \frac{a}{b} \times 100$$

Where:

a weight in g of extract, and

b weight in g of specimen used.

Annex B
(Normative)

Determination of free sulphur from acetone extractable matter in rubber teats

B.1 Outline of the Method

Free sulphur in the acetone extract is determined by the acid digestion method. In this method, the sample is treated with an oxidising acid such as nitric and an auxiliary agent such as bromine, at an elevated temperature. By this oxidation sulphur is converted to sulphate, in which form it is estimated gravimetrically.

B.1.1 Reagents

B.1.1.1 Bromine ─ saturated bromine water

B.1.1.2 Nitric Acid with a specific gravity 1.50

B.1.1.3 Zinc nitric acid Solution ─ Add 200 g of Zinc oxide to one litre of nitric acid with a specific gravity 1.42.

B.1.1.4 Potassium Chlorate Crystals

B.1.1.5 Picric Acid - saturated solution.

B.1.1.6 Barium Chloride Solution ─ 100 g/litre and

B.1.1.7 Hydrochloric Acid

B.1.2 Procedure

B.1.2.1 Add to the flask containing the acetone extract, 10 ml of zinc-nitric acid solution and 2 to 3 ml of bromine and cover with a watch glass. Allow to stand near a steam plate for 30 minutes, then heat on the steam plate to a foamy syrup.

B.1.2.2 Add 10 ml of nitric acid and heat on the hot plate with the cover removed until all bromine is expelled. Continue if organic matter or carbon remains at this point, add a few millilitres of nitric acid and a few crystals of potassium chlorate and evaporate at boiling. Repeat this operation until all carbon is removed and the solution is clear, colourless, or light yellow.

At this point either of the following methods may be used.

B.1.2.3 Method A ─ Place the flask on an asbestos gauze and evaporate the mixture to dryness over a burner. Then bake the mixture at the highest temperature of the burner until all nitrates are decomposed and no more nitrogen oxide fumes can be detected. The flask and its contents must be carefully annealed after this procedure by gradually decreasing the flame or by placing the flask on successively cooler source of heat.

B.1.2.4 Method B ─ Evaporate the mixture, cool, add 10 ml of hydrochloric acid, and evaporate to dryness, avoiding spattering. Repeat this procedure once, or more, if oxides of nitrogen are still evolved.

B.1.2.5 Cool the flask, add 50 ml of hydrochloric acid (1:6) .and digest hot until solution is as complete as possible. Filter while hot. Wash the filter and dilute the filtrate and washings using distilled water to about 300 ml.

B.1.2.6 .Add 10 ml of saturated picric acid solution, heat to 90 ˚C, and precipitate the sulphate by dropwise addition of barium chloride solution while stirring vigorously. Digest the precipitate overnight, preferably at 60 ˚C to 80˚C, using a watch glass to cover the beaker.

B.1.2.7 Filter the barium sulphate and- wash with distilled water until the filtrate is colourless. Dry, incinerate, and finally ignite the precipitate at 650 ˚C to 900°C to constant weight. Cool in a desiccator and weigh

B.1.3 Calculation

Calculate the percentage of sulphur as follows:

$$\text{Sulphur, \%, by weight} = \frac{A \times 0.1373 \times 100}{B}$$

Where:

A weight in g of barium sulphate and

B weight in g of specimen used.

Annex C
(Normative)

Change in physical properties

C.1 Change in physical properties

C.1.1 Outline of the Method ─ Teats are autoclaved for a known time at constant temperature and the change in physical properties of teats, as examined visually, is reported

C.1.2 Procedure ─ Take three teats and autoclave them in 250 ml of water for one hour at 120˚C ± 5˚C. Cool the autoclave to room temperature and keep the water extract for further test in (C.2). Keep the teats in an air-oven maintained at 120˚C ± 2°C for one hour, and examine the teats after cooling to room temperature for any sign of deterioration such as tackiness, hardness, crackiness and discolouration.

C.2 Water extract

Examine the water extract as obtained under C.1.2 for any colour, odour and turbidity imparted to the water.

Annex D
(Normative)

Determination of pH value of water extract

D.1 Outline of the Method

The pH value of the water extract is determined electrometrically with the help of the glass electrode, by direct reading method.

D.1 Apparatus

D.1.1 Beaker ─ A glass beaker of sufficient size to accommodate the sample used

D.1.2 Metallic Container ─ Made of stainless steel or copper for boiling water

D.1.3 pH Meter ─ Equipped with glass and calomel electrodes to read directly pH having an accuracy of ± 0.05 pH

D.1.4 Watch Glass

D.2 Procedure

D.2.1 Boil the sample for 15 minutes in water and decant the extract into the container.

D.2.2 Let the mixture cool to room temperature in an atmosphere free from chemical fumes which might contaminate the samples.

D.2.3 Decant off any supernatant liquid. Place the electrodes in the sludge and rotate the beaker gently in alternate direction until a constant pH value is obtained. Repeat the procedure on a second sample.

NOTE 1 ─ To prevent contamination of the sample during boiling, a clean watch- glass may be used over the beaker.

NOTE 2 ─ Standardize the pH meter with a reliable buffer in the pH range of the aqueous extract samples to be tested.

NOTE 3 ─ The distilled water used in the test should be as pure as possible. The pH of the freshly boiled distilled water shall be 6.9 ± 7.1

D.3 Report

The report shall include the following:

a) Proper identification of the sample and

b) Result obtained from the two individual determinations and their average.

Annex E
(Normative)

Deformation under Tension test

E.1 Apparatus

E.1.1 Cutting tools for preparing the sample.

E.1.2 Tensile testing machine and clamping accessories.

E.1.3 Measuring steel tape or meter rule capable of measuring accurately to ±0.5mm.

E.1.4 Timer accurate to ±1s.

E.2 Procedure

E.2.1 Cut out the rim of the teat and cut it open to form a band.

E.2.2 Mark two reference lines 25mm apart in the centre of the band.

E.2.3 Connect the band to a tensile testing machine and stretch it up-to 75mm and hold for 10mins.

E.2.4 Release the band and measure distance between the reference lines, l.

E.3 Expression of results.

Calculate the permanent deformation/ elongation under tension expressed as a percentage of original length.

$$\text{Percentage deformation/elongation} = \frac{(l - 25)\text{mm}}{25\text{mm}} \times 100$$

Annex F
(Normative)

Determination of tear resistance

F.1 Apparatus

F.1.1 Pressure testing machine

F.1.2 Press bar, ported from nichrome high chrome steel, grade H13 (H13 high chrome tool steel) or equivalent. It has a hardness of at least 50 Rockwell C, its shape and dimensions are shown in Figure 2, and it can be used with a pressure testing machine.

F.1.3 The punching plate, made of plastic, has a hardness (70 ± 5) Shore D

F.1.4 Tensile Strength Tester

F.1.5 Equipment suitable for holding various parts of the rubber teat

F.2 Test method

F.2.1 Place the viewing part of the rubber tip on the punching plate

F.2.2 Adjust the push rod connected to the pressure test apparatus so that the center of the blade is Well, upright and perpendicular to the axis of the teat and about 15 mm to 20 mm from the top of the tip, measured along the axis of the tip of the teat, see Figure F1. In case the cross section of the used part does not look circular Adjust the press bar to match the sharp flat part of the rubber teat head.

F.2.3 Press the push rod onto the rubber tip at a rapid rate (10 ± 5) mm/min until a compression force (200 ± 10) N is achieved. This pressure is maintained for a period of time. (1 ± 0.5) s

F.2.4 Inspect the puncture mark on the teat head. If the rubber teat is pierced through both sides of the wall, continue the test in the next item. Please do this test without having to continue with the next test.

F.2.5 Fix the tip and base of the rubber tip that was pierced through both sides of the wall by means of a fixing device

F.2.6 Attach the device attached to the tensile tester so that the tension is aligned with the axis of the rubber nipple. Adjust the tip to align along the axis of the teat with a clamping force (5 ± 2) N, then pull it with a fast speed (200 ±10) mm/min until a tensile (90 ± 5) N is maintained for a period of (10 ± 0.5) s.

F.2.7 Examine the damage that has been caused by the hustle and bustle

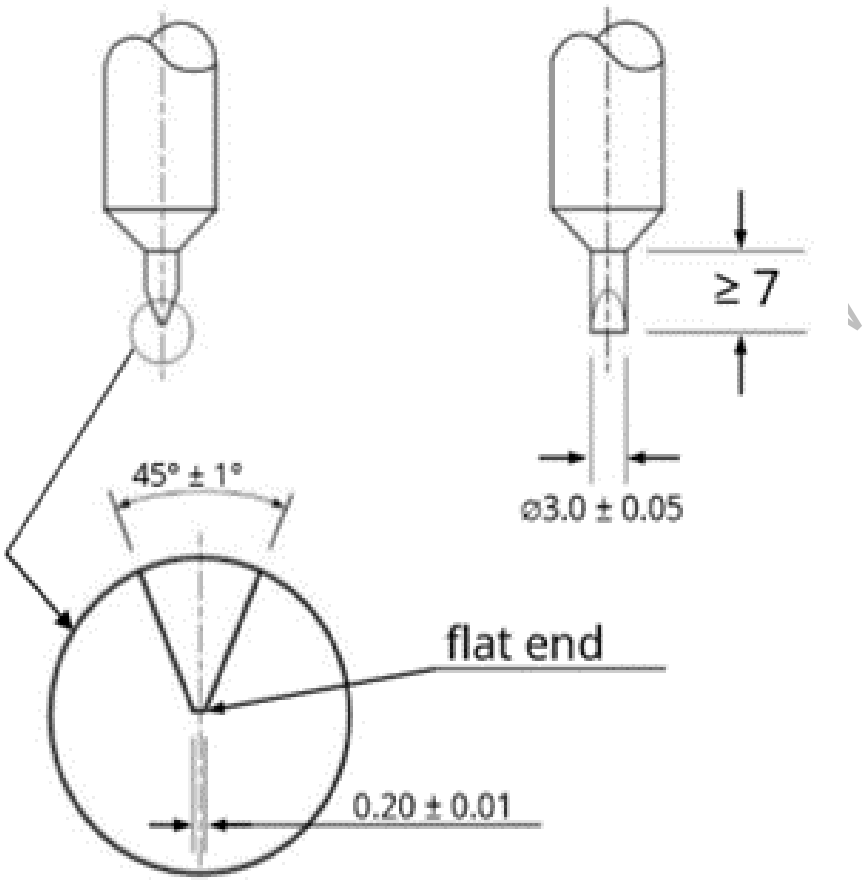

Figure 1 – The shape and size of the pressed bar

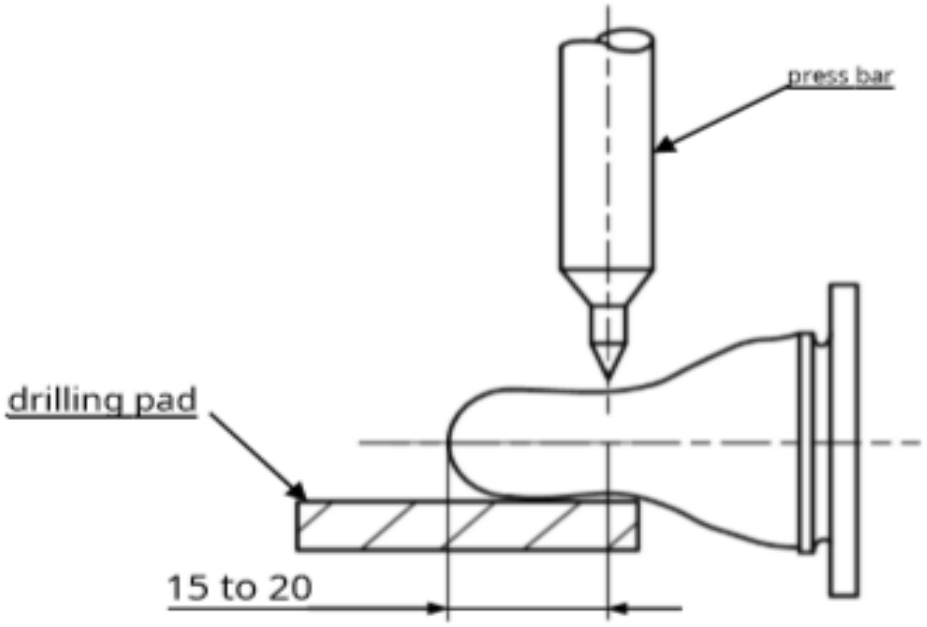

Figure 2 – Location of the puncture of the teat head

Fig.

Annex G
(Normative)

Resistance to sudden temperature changes

G.1 Test method

G.1.1 The rubber teats are soaked in boiled distilled water for a period of time (10 ± 1) min without making contact with the container.

G.1.2 The teat is boiled and immediately immersed in distilled water at a temperature (5 ± 2) °C for (10 ± 1) min.

G.1.3 Check to determine the damage caused to the rubber.

Annex H
(Normative)

Determination of N-nitrosamines and N-nitrosatable content

H.1 Release-test liquid (saliva test solution)

To obtain the release-test liquid, dissolve 4.2 g of sodium bicarbonate ($NaHCO_3$.), 0.5 g of sodium chloride (NaCl), 0.2 g of potassium carbonate (K_2CO_3,) and 30.0 mg of sodium nitrite ($NaN0_2$) in one litre of distilled water or water of equivalent quality. The solution must have a pH value of 9 0.

H.2 Test conditions

Samples of material obtained from an appropriate number of teats or soothers are immersed in the test release liquid for 24 hours at a temperature of 40 ± 2 ° C.

H.3 Determining the release of N-nitrosamines and N-nitrosatable substances

H.3.1 The release of N-nitrosamines is determined in one aliquot of each solution obtained according to H.2. The N-nitrosamines are extracted from the aliquot with nitrosamine-free dichloromethane (DCM) and determined by gas chromatography.

H.3.2 The release of N-nitrosatable substances is determined in another aliquot of the solution obtained according to H.2 The nitrosatable substances are converted into nitrosamines by acidification of the aliquot with hydrochloric acid. Subsequently the nitrosamines are extracted from the solution with DCM and determined by gas chromatography.

Annex I
(Normative)

Bottle adhesion test

I.1 Apparatus

I.1.1 Equipment for holding the baby feeding bottle so that the horizontal plane is at an angle of 45° (see Figure F.I).

I.1.2 Equipment suitable for holding the rubber tip and can be connected to the tensile tester.

I.1.3 Tensile testing machine

I.2 Test method

I.2.1 Assemble the rubber cap to the baby feeding bottle filled with a liquid to nominal capacity

I.2.2 Hold the baby feeding bottle so that the horizontal plane is at an angle of 45° (see Figure F.I).

I.2.3 Using the fixing device secure the loose tip of the rubber teat (10 ± 2) mm from the tip of the rubber teat.

I.2.4 Connect the clamping device to the tensile tester and gently pull the teat in line.at a rapid rate (200 ± 10) mm/min until a tensile of (60 ± 5) N is obtained and hold for (10 ± 0.5) s

I.2.5 Examine the damage caused to the rubber teat and the leakage from the baby feeding bottle.

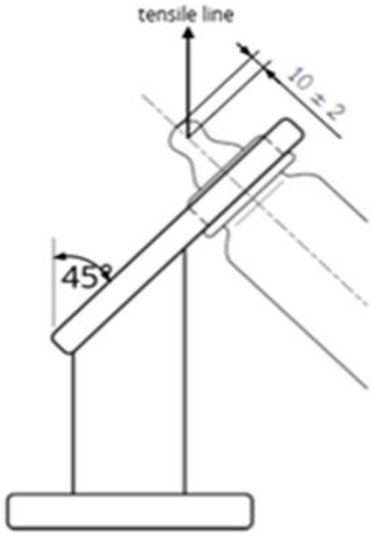

Figure FI – Bottle adhesion test

Annex J
(Normative)

Sampling of rubber teats for feeding bottles

J.1 General Requirements of sampling

J.1.1 Precautions shall be taken to protect the samples, the material being sampled and the containers for samples from adventitious contamination.

J.1.2 The samples shall be placed in clean, dry and airtight glass or other suitable containers on which the material of the teats has no action.

J.1.3 The sample containers shall be of such size that they are almost completely filled by the sample.

J.1.4 Each sample container shall be sealed air tight and marked with full details of sampling, the date of sampling and the year of manufacture of teats.

J.2 Scale of sampling

J.2.1 Lot ─ All the rubber teats for feeding bottles of the same size and manufactured from the same raw materials under similar conditions of manufacture in one consignment shall constitute a lot.

J.2.2 Samples shall be tested from each lot separately, for ascertaining conformity of a lot to the requirements of this specification. _

J.2.3 The number of teats to be selected in the sample from a lot shall depend upon the size of the lot and shall be in accordance with Table J1.

Table J1 ─ Scale of sampling and acceptance number

SN	**No. of teats in the lot**	**No. of teats to be selected in the samples**	**Permissible No. of defective teats for workmanship and finish**	**Number of tests to be carried out for each of the other characteristics**
1	Up to 300	9	1	1
2	301 to 1000	18	1	1
3	1001 to 3500	27	2	2
4	3501 and above	45	3	3

J.2.4 Although it is not possible to lay down any fixed rule as to how the samples are to be selected from the packages, it is desirable that the teats be drawn evenly from as many packages as possible. However, it is recommended that at least 10 percent of the packages should be selected and an equal number of teats drawn at random from each package selected to give the required number of teats in accordance with col 3 of Table J1.

J.3 Number of tests and criteria for conformity

J.3.1 Workmanship and Finish

J.3.1.1 All the teats selected in the sample shall be inspected for workmanship and finish in accordance with 4.1. A teat shall be considered to be defective, if it fails to satisfy the requirements of workmanship and finish in any one or more respect.

J.3.1.2 A lot shall be considered as having satisfied the requirements of workmanship and finish, if the number of defective teats found as in J.3.1.1 does not exceed the applicable permissible number of defective teats.

J.3.1.3 For determining the conformity of the lot to the requirements of: acetone extractable matter, free sulphur in acetone extract, change in physical properties, water extract (colour, odour, turbidity), pH of water extract, tension test, tear resistance, temperature, N-nitrosamines, N-nitrosatable and bottle adhesion. The number of tests to be carried on a lot per requirement, shall be in accordance with col 5 of Table J1. For carrying out these tests, the rubber teats as selected under col 3 of Table J1 and found satisfactory for workmanship and finish shall be used. In case additional number of teats are required for these tests, they shall also be selected at random from the packages already used for drawing the samples.

J.3.1.4 All the test results for the different characteristics shall satisfy the requirements of the specification individually

Bibliography

[1] IS 3565:1966, S*pecification for rubber teats for feeding bottles*

[2] TIS 969-2562, *Rubber nipples for feeding bottles*

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