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Indian Standard SPECIFICATION FOR RUBBER TEATS FOR FEEDING BOTTLES

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Indian Standard SPECIFICATION FOR RUBBER TEATS FOR FEEDING BOTTLES

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(Continued on page 2)

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IS: 3565 - 1966

(Continued from page 1)

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Indian Standard SPECIFICATION FOR RUBBER TEATS FOR FEEDING BOTTLES

0. FOREWORD

- **0.1** This Indian Standard was adopted by the Indian Standards Institution on 18 April 1966, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Chemical Division Council.
- 0.2 It is not uncommon to find that teats often contain harmful ingredients which are likely to go into the solution and contaminate the milk or liquid baby food. Further, they often impart undesirable odour, taste or discolouration and also cause irritation to the feeding baby, becoming hard at times. Some of the rubber ingredients are also harmful to the baby and may cause, in acute cases, contact dermatitis.
- 0.3 Taking into consideration the human aspect involved, the Rubber Products Sectional Committee decided to formulate a national standard on the subject in order to make the teats harmless and aggreable to the baby. This standard prescribes physical and chemical requirements for teats. The Committee, while formulating the standard, took due note of the lack of facilities for conducting certain biological tests on rubber teats. In the absence of such tests, it is hoped that the accelerators recommended in the standard are strictly adhered to during the manufacture of teats. However, other accelerators, if guaranteed against contact dermatitis and harmful contamination, could be used in the manufacture of teats. The Committee was also in favour of prescribing shapes and sizes for the teats but decided to leave it to the purchaser and the supplier in the absence of standard dimensions for necks of feeding bottles.
- 0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS: 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements for rubber teats for feeding bottles.

^{*}Rules for rounding off numerical values (revised).

2. REQUIREMENTS

2.1 Material

- 2.1.1 The teats shall be made from rubber together with necessary compounding and vulcanizing ingredients. These shall be made from solid rubber or latex and shall be free from grits, reclaimed rubber or vulcanized waste. The rubber mix shall not include any ingredient known to be injurious or poisonous to human beings.
- 2.1.2 All ingredients used shall be free from harmful substances liable to extraction by contact with milk or which may cause the development of undesirable odour, taste or discolouration. Softeners and organic accelerators and antioxidants, if incorporated, shall not impart an undesirable odour or taste to the finished teats. The following accelerators are recommended:
 - a) Dithiocarbamates, and
 - b) Appropriate Derivatives of Mercaptobenzthiazole.
- 2.2 Workmanship and Finish The teats shall be transparent or translucent and shall be free from patches, blisters, porosity, embedded foreign matter and physical defects when examined visually.
- 2.2.1 Shape and Size The shape and size of the rubber teats shall be as agreed to between the purchaser and the supplier.
- 2.3 Acetone Extract The teats shall not yield more than three percent of extractable matter when extracted with hot acetone (B-1).
- 2.4 Free Sulphur in Acetone Extract The amount of free sulphur (B-2) in the finished product shall not exceed 0.2 percent by weight.
- 2.5 Change in Physical Properties The teats shall not show any sign of deterioration such as tackiness, hardness, crackiness and discolouration, when subjected to autoclaving (B-3).
- 2.6 Properties of Water Extract The teats shall not impart any colour, odour or turbidity to water extract (B-4).
- 2.7 pH of the Water Extract The pH of the water extract (B-5) shall be 7.0 ± 0.5 .
- 2.8 Tension Set The tension set (B-6) shall not be more than 20 percent.

3. MARKING AND PACKING

- 3.1 Marking Each teat or package or both shall be legibly marked with the following:
 - a) Manufacturer's name or trade-mark, if any;

- b) Number of teats in each package; and
- c) Batch number or month and year of manufacture.
- 3.1.1 Each teat or package or both may also be marked with the ISI Certification Mark.

Note — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

3.2 Packing — Each teat may be packed in polyethylene covers and put into a carton.

4. SAMPLING

4.1 For the purpose of ascertaining the conformity of the rubber teats, in a consignment, to this specification, the scale of sampling and criteria for conformity shall be as prescribed in Appendix A.

5. TEST METHODS

- 5.1 Standard Atmospheric Conditions for Physical Tests Unless otherwise required by the particular method of test, the test specimens shall be conditioned to a moisture equilibrium in an atmosphere of 65 ± 2 percent relative humidity and temperature of $27^{\circ} \pm 2^{\circ}$ C (see IS: 196-1950*) and if possible, tested in that atmosphere, or soon after removal from that atmosphere.
- 5.2 Quality of Reagents Unless specified otherwise, pure chemicals (Note) and distilled water (conforming to IS: 1070-1960†) shall be employed in tests.

Note — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

5.3 Tests regarding acetone extract, free sulphur in acetone extract, determination of change in physical properties, determination of properties of water extract, pH of water extract and tension set shall be done in accordance with the method prescribed in Appendix B.

^{*}Atmospheric conditions for testing. †Specification for water, distilled quality (revised).

APPENDIX A

(Clause 4.1)

SAMPLING OF RUBBER TEATS FOR FEEDING BOTTLES

A-1. GENERAL REQUIREMENTS OF SAMPLING

- A-I.1 Precautions shall be taken to protect the samples, the material being sampled and the containers for samples from adventitious contamination.
- A-1.2 The samples shall be placed in clean, dry and air-tight glass or other suitable containers on which the material of the teats has no action.
- A-1.3 The sample containers shall be of such size that they are almost completely filled by the sample.
- A-1.4 Each sample container shall be sealed air-tight after filling and marked with full details of sampling, the date of sampling and the year of manufacture of teats.

A-2. SCALE OF SAMPLING

- A-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.
 - A-2.1.1 Samples shall be tested from each lot separately, for ascertaining conformity of a lot to the requirements of this specification.
 - A-2.2 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 1.

TABLE 1 NUMBER OF TEATS TO BE SELECTED FROM A LOT AND PERMISSIBLE NUMBER OF DEFECTIVES

No. of Teats in the Lot	No. of Teats to BE SELECTED IN THE SAMPLES	PERMISSIBLE NO. OF DEFECTIVE TEATS FOR WORKMANSHIP AND FINISH	No. of Tests to be Performed for Other Charac- teristics
(1)	(2)	(3)	(4)
Up to 3 000	90	2	1
3 001 ,, 10 000	180	4	2
10 001 ,, 35 000	270	6	3
35 001 and above	450	8	5

A-2.2.1 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 2 of Table 1.

A-3. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

- A-3.1 Workmanship and Finish All the teats selected in the sample A-2.2.1 shall be inspected for workmanship and finish in accordance with 2.2 and 2.2.1. 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.
- A-3.1.1 A lot shall be considered as having satisfied the requirements of workmanship and finish, if the number of defective teats found as in A-2.1 does not exceed the applicable permissible number of defective teats.
- A-3.2 For determining the conformity of the lot to the requirements of, acetone extractable matter, free sulphur in acetone extract, change in physical properties of water extracted teat and water extract, pH of water extract and tension set the number of tests to be carried on a lot, shall be in accordance with col 4 of Table 1 (see A-2.2). For carrying out these tests, the rubber teats as selected under col 2 of Table 1 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.
- A-3.2.1 All the test results for the different characteristics shall satisfy the requirements of the specification individually.

APPENDIX B

(Clause 5.3)

TEST METHODS

B-1. DETERMINATION OF ACETONE EXTRACTABLE MATTER FROM RUBBER TEATS

B-1.1 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 preferably by heating on a water bath. The extracted matter in the flask is freed from

IS: 3565 - 1966

the solvent and its contents are finally dried at a constant temperature, cooled and weighed.

B-1.2 Procedure — 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. 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). 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. 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. 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.

B-1.3 Calculation — Calculate the percentage of the acetone extract as follows:

Acetone extract percent =
$$\frac{A}{B} \times 100$$

where

A = weight in g of extract, and B = weight in g of specimen used.

B-2. DETERMINATION OF FREE SULPHUR FROM ACETONE EXTRACTABLE MATTER IN RUBBER TEATS

B-2.1 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-2.2 Reagents

B-2.2.1 Bromine — saturated bromine water

B-2.2.2 Nitric Acid - sp gr 1.50 (see IS: 264-1950*).

^{*}Specification for nitric acid.

- **B-2.2.3** Zinc-Nitric Acid Solution Add 200 g of zinc oxide to one litre of nitric acid (sp gr 1.42).
 - B-2.2.4 Potassium Chlorate Crystals
 - B-2.2.5 Picric Acid saturated solution.
 - B-2.2.6 Barium Chloride Solution 100 g/litre.
 - B-2.2.7 Hydrochloric Acid (see IS: 265-1962*).
- B-2.3 Procedure 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 vatch glass. Allow to stand near a steam plate for 30 minutes, then heat on the steam plate to a foamy syrup. Add 10 ml of nitric acid and heat on he 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.
 - B-2.3.1 At this point either of the following methods may be used.
- **B-2.3.1.1** Method A Place the flask on an asbestos gauze and evaporate the mixture to dryness over a Tirrill 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-2.3.1.2** 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-2.3.2** 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 to about 300 ml. 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° to 80°C, using a watch glass to cover the beaker. Filter the barium sulphate and wash with water until the filtrate is colourless. Dry, incinerate, and finally ignite the precipitate at 650° to 900°C to constant weight. Cool in a desiccator and weigh.
- **B-2.4 Calculation** Calculate the percentage of sulphur as follows:

Sulphur, percent by weight =
$$\frac{A \times 0.137 \ 3 \times 100}{B}$$

^{*}Specification for hydrochloric acid (revised).

IS: 3565 - 1966

where

A = weight in g of barium sulphate, and B = weight in g of specimen used.

B-3. CHANGE IN PHYSICAL PROPERTIES

- **B-3.1 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.
- **B-3.2 Procedure** Take three teats and autoclave them in 250 ml of water for one hour at $120^{\circ} \pm 5^{\circ}$ C. Cool the autoclave to room temperature and keep the water extract for further test (**B-4**). Keep the teats in an air-oven maintained at $120^{\circ} \pm 2^{\circ}$ 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.

B-4, WATER EXTRACT

B-4.1 Examine the water extract as obtained under B-3.2 for any colour, odour and turbidity imparted to the water.

B-5. DETERMINATION OF PH VALUE OF WATER EXTRACT

B-5.1 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.

B-5.2 Apparatus

- **B-5.2.1** Beaker A glass beaker of sufficient size to accommodate the sample used.
- **B-5.2.2** Metallic Container made of stainless steel or copper for boiling water.
- **B-5.2.3** pH Meter equipped with glass and calomel electrodes to read directly pH having an accuracy of ± 0.05 pH.

B-5.2.4 Watch-Glass

B-5.3 Procedure — Boil the sample for 15 minutes in water and decant the extract into the container. Let the mixture cool to room temperature in an atmosphere free from chemical fumes which might contaminate the samples. Decant off any supernatant liquid. Place the electrodes in the sludge and rotate the beaker gently in alternate direction until a constant bH 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 to 7.1.

B-5.4 Report — The report shall include the following:

- a) Proper identification of the sample, and
- b) Result obtained from the two individual determinations and also their average.

B-6. TENSION SET

B-6.1 Procedure — Cut out the rim of the teat and cut it open to form a band. Mark two reference lines 25 mm apart in the centre of the band and stretch it up to 75 mm; hold it in that position for 10 minutes and then release. Measure the distance between the reference lines after 10 minutes.

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^{*}Under print.