भारतीय मानक Indian Standard

IS 14625: 2015

प्लास्टिक की दूध पिलाने की बोतलें

(पहला पुनरीक्षण)

Plastics Feeding Bottles

(First Revision)

ICS 83.08; 55.100

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FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Plastic Containers Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

Feeding bottles are universally used for feeding infants. An Indian Standard on 'Glass Feeding Bottles' is published as IS 5168: 1969. Over the last few decades plastics have become indispensable and have taken over glass, metal and paper as a material of choice in many sectors. In view of the convenience in usage plastics have become an automatic choice in the manufacturing of feeding bottles.

Section 11(2) of *The Infant Milk Substitutes, Feeding Bottle and Infant Foods (Regulation of Production, Supply and Distribution) Act*, 1992 states that 'No person shall sell or otherwise distribute any feeding bottle unless it conforms to the Standard Mark specified by the Bureau of Indian Standards referred to in sub-section (1) for feeding bottles and such mark is affixed on its container'. The Act has been subsequently amended as *The Infant Milk Substitute, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act*, 2003. As per Section 2(c) of this Act, 'feeding bottle' means any bottle or receptacle used for the purpose of feeding infant milk substitutes, and includes a teat and a valve attached or capable of being attached to such bottle or receptacle.

These considerations led the Committee to formulate a specification for plastics feeding bottles in 1999. This standard covered polycarbonate (PC), polypropylene (PP) and polyethersulfone (PES) as raw material for manufacturing plastics feeding bottles owing to their excellent transparency and sterlizability.

Bisphenol A, having chemical formula $(CH_3)_2C(C_6H_4OH)_2$, [IUPAC name: 4,4'-(propane-2,2-diyl) diphenol] is a building block monomer for polycarbonate resin that in turn is used to manufacture infant feeding bottles. It is used to make them clear and nearly shatter-proof.

Recently through studies, serious concerns have been raised about the polycarbonate type of plastic bottles because they contain Bisphenol A (BPA) which has serious health concerns even in very low dosages. It has been reported that BPA containing plastic feeding bottles leached high levels of Bisphenol A which is harmful for infants.

Accordingly, BPA has been banned for use in manufacturing infant feeding bottles by many countries including US, EU, Canada, Australia, Brazil, Malaysia, China etc.

In this revision all modifications carried out through five amendments on previous version have been incorporated. Use of polycarbonate as a material for manufacturing infant feeding bottles have been deleted in view of reports on Bisphenol A and olefin based polymers as material for manufacture of feeding bottles have been included.

While formulating this standard considerable assistance has been derived from the following publications:

MS~735:2012 'Specification for plastic feeding bottles', issued by Standards and Industrial Research Institute of Malaysia, Malaysia

EN 14350-1: 2004 'Child use and care articles — Drinking equipment: Part 1 General and mechanical requirements and tests'

EN 14350-2: 2004 'Child use and care articles — Drinking equipment: Part 2 Chemical requirements and tests'

Code of Federal Regulations Title 21, Volume 3 CITE: 21CFR177.1580 Revised as of April 1, 2012

Indian Standard

PLASTICS FEEDING BOTTLES

(First Revision)

1 SCOPE		IS No./International	Title
	bes the requirements and methods for infant plastic feeding bottles	Standard	for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water (<i>first revision</i>)
2 REFERENCES		9845 : 1998	Determination of overall
through reference in this standard. At the indicated were vali- revisions, and partic standard are encoura	below contain provisions which, this text, constitute provisions of time of publication, the editions d. All standards are subject to es to agreements based on this ged to investigate the possibility trecent editions of the standards	10909 : 2001	migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (second revision) Positive list of constituents of polypropylene and its copolymers in contact with foodstuffs, pharmaceuticals and
IS No./International Standard 249: 1979	Title Specification for sodium bichromate, technical (third revision)	10910 : 1984	drinking water (<i>first revision</i>) Specification for Polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking
266 : 1993	Sulphuric acid — Specification (third revision)	14534 : 1998	water Guidelines for recycling of
1070 : 1992	Reagent grade water — Specification (third revision)	15303 : 2003	plastics Determination of antimony, iron
1699 : 1995 2798 : 1998	Methods of sampling and test for food colours (<i>first revision</i>) Methods of test for plastics	ASTM D 1002 - 201	and selenium in water by electrothermal atomic absorption spectrometric method 3 Standard test method for haze
3025	containers (first revision) Methods of sampling and test (physical and chemical) for		and luminous transmittance of transparent plastics
(Part 37) : 1988	water and waste water Arsenic (first revision)	3 TERMINOLOG	
(Part 41) :1992 (Part 47) : 1994	Cadmium (first revision) Lead (first revision)	For the purpose of the in IS 7019 and the fo	is standard, the definitions given bllowing shall apply.
(Part 48) : 1994 (Part 52) : 2003	Mercury (first revision) Chromium (first revision)	3.1 Accessories — stopper, teat, and cap	It shall include the hood, disc/oring.
(Part 56) : 2003 3565 : 1966	Selenium (first revision) Specification for rubber teats for feeding bottles Methods for random sampling		sory — Any device other than a ermits a child to obtain fluid from apple feeding spout.
4905 : 1968 7019 : 1998	Methods for random sampling Glossary of terms in plastics and flexible packaging excluding		nollow tube drinking accessory
8747 : 1977	paper (second revision) Methods of tests for environmental stress-crack	3.3 Container — receptacle.	It is either a feeding bottle or
9833 : 2014	resistance of blow moulded polyethylene containers List of pigments and colourants	of holding a fluid an	e — A container which is capable ad incorporates a graduated scale measurement and is intended for

feeding a child through a feeding teat or drinking accessory.

- **3.4 Locking Ring** A component used to secure a feeding teat or drinking accessory to the container.
- **3.5** Sealing Disc A component used to create a seal between the container and the locking ring.
- **3.6 Protective Cover** A component as safety shield to cover a feeding teat or drinking accessory.
- **3.7 Matched Components** Any of the above defined components which are used together whilst feeding a child.
- **3.8 Nominal Capacity** The volume of milk/fluid normally expected to be filled in the bottles at $27 \pm 2^{\circ}$ C.
- **3.9 Brimful Capacity** The volume of water required to fill the bottle completely to brim level at $27 \pm 2^{\circ}$ C.
- **3.10 Re-usable** A component intended to be used again after first use.
- **3.11 Numbered Graduations** The numbered markings which indicate the volume of fluid within the feeding bottle.
- **3.12 Single-use Feeding Teat, Drinking Accessory or Container** Any item of drinking equipment sold for single-use.
- **3.13 Protrusions** A drinking accessory, feeding teat or spoon, excluding straws or anything extruding from physical contour of the feeding device.
- **3.14 Receptacles** A container used for holding or storing the things.

4 MATERIALS

4.1 The material used for plastics feeding bottles and accessories excluding teats shall be of polypropylene conforming to IS 10910 or polyethersulfone (PES) or any other olefin based polymer, co-polyester material or other raw material as given in Annex A for manufacture of plastic feeding bottle. The materials used should be of no health hazards to babies and shall not contain Bisphenol A (BPA).

NOTE — Polyvenyl chloride (PVC) and polyethylene terephthalate (PET) shall not be used to manufacture feeding bottles.

4.2 Teats shall conform to IS 3565.

5 REQUIREMENTS

5.1 Physical Requirements

5.1.1 Description

The feeding bottle shall be of suitable design, shape

and required dimensions as agreed to between the purchaser and the supplier. However, the shape shall be such that it is easily cleanable and does not permit the food remnants to remain stuck inside the feeding bottles. Neck shall be smooth from inside that is solid without any underside grooves.

Figures 1 and 2 illustrate typical examples of different items of drinking equipment and their design features. Figures 1 and 2 are illustrative and for information only.

- **5.1.2** Manufacture, Workmanship, Finish and Appearance
- **5.1.2.1** The bottles and accessories shall be manufactured by a suitable process adhering to good manufacturing practice (GMP).
- **5.1.2.2** The body of the bottle shall be smooth, both internally and externally, free from any visual defects like cavities, crevices, hooks, embedded foreign matters, detrimental bubbles, streaks, flaws, stains, etc. All components of plastic feeding bottle when assembled for use shall be free from points and edges and any harmful extrusions, which are likely to cause injury. All parts which are designed to be detached (example, for cleaning) shall not fit entirely within the small parts cylinder in any orientation and without compression.

5.1.3 Wall Thickness

The minimum wall thickness shall be declared by the manufacturer. The wall thickness when measured in accordance with **4.5** of IS 2798 shall not be less than the declared minimum value.

5.1.4 Capacity

5.1.4.1 The bottles shall be manufactured in nominal capacity of 125 ml, 150 ml and 250 ml or any other capacity as agreed to between the purchaser and the supplier. The brimful capacity shall exceed the nominal capacity by a minimum of 15 percent.

5.1.4.2 Capacity scale

All feeding bottles shall be marked with graduations at least in millilitres. The feeding bottles shall be provided with the following capacity scale:

- a) If the feeding bottle is unprinted, then capacity scale shall be engraved on the bottle and if the bottle is printed then the capacity scale shall be clearly printed. The bottles with printed scale shall be tested for the permanency of pigment in accordance with method described in Annex B.
- b) The scale interval and the maximum indicating scale mark shall be as agreed to between the purchaser and the supplier. However, the

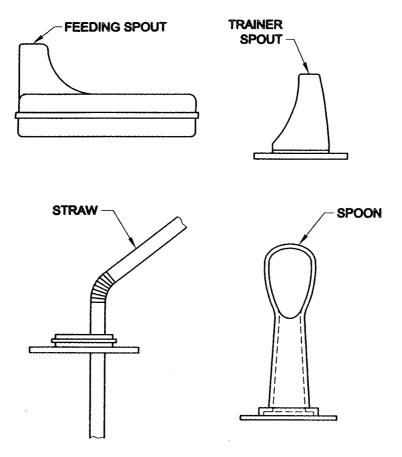


Fig. 1 Example of Drinking Accessories

minimum scale mark and interval marking shall be not more than 20 percent of the maximum scale indicating mark.

 The scale marks and the indicating numerical values shall be clear and shall not be affected by high temperature sterilizing treatment.

5.2 Chemical Requirements

5.2.1 Migration of Certain Elements

5.2.1.1 *Principle*

Soluble elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium) are extracted from the individual components of the drinking equipment that are accessible to the child. Conditions that stimulate contact with stomach acid shall be used. The concentrations of the soluble elements are described quantitatively.

5.2.1.2 Apparatus

5.2.1.2.1 Water bath, able to maintain the temperature of the test mixture at 37 ± 2 °C and having the means to agitate the test mixture.

5.2.1.2.2 pH meter, with an accuracy of ± 0.2 pH units.

5.2.1.2.3 *Membrane filter*, with a pore size of 0.45 µm.

5.2.1.2.4 *Centrifuge*, capable of centrifuging at 5 000 \pm 500 rpm.

5.2.1.3 Reagents

Unless specified otherwise, pure chemicals and distilled water (see IS 1070) shall be employed in tests.

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

5.2.1.3.1 *Hydrochloric acid solution*, 0.07 ± 0.00 mol/l.

5.2.1.3.2 *Hydrochloric acid solution*, 2.0 ± 0.2 mol/1.

5.2.1.3.3 Distilled water

5.2.1.4 *Selection of test portions*

Test portions shall be taken from each individual component of the drinking equipment that is accessible to be child. Components that are joined together shall be separated and tested as separate items.

5.2.1.5 *Preparation of test portion*

At least 100 mg and preferably at least 1 g, of a representative test portion of each individual component of the drinking equipment shall be obtained. Heating of the materials, whilst separating components and during cutting into pieces, shall be avoided.

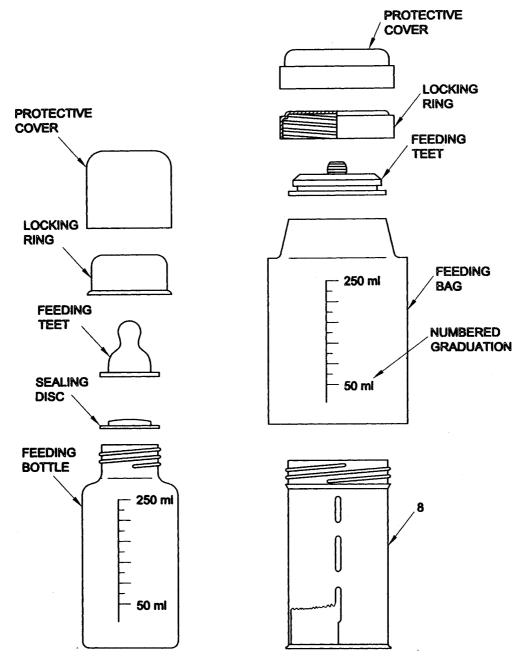


Fig. 2 Examples of Containers with Feesding Teats

Feeding teats shall be cut length-wise only once. All other components shall be cut, as far as possible, into pieces of length 4 - 6 mm and width not exceeding 6 mm.

5.2.1.6 Procedure

Mix at 37 ± 2 °C, the prepared test portion (*see* **5.2.1.5**) with 50 times its mass of an aqueous solution of the hydrochloric acid (*see* **5.2.1.3.1**) in a container of 1.5 to 5 times the volume of acid. Agitate the container in the water bath (*see* **5.2.1.2.1**) for 60 ± 5 s and determine the acidity of the mixture with the *pH* meter (*see* **5.2.1.2.2**). If the *pH* is greater than 1.5, add drop-

wise, whilst continuing to shake the mixture, an aqueous solution of hydrochloric acid (see **5.2.1.3.2**) until the pH is in the range of 1.0 to 1.5. The mixture shall be protected from light and continuously agitated under similar conditions for a further 60 ± 1 min before being allowed to stand for 60 ± 1 min at the same temperature.

Immediately after standing, separate the solid from the solution by membrane filtration (*see* **5.2.1.2.3**) and, if necessary, centrifugation (*see* **5.2.1.2.4**) at up to 5 000 rpm and for no longer than 10 min. The use of centrifugation shall be reported.

If the solutions are to be kept for more than 1 day prior to analysis, they shall be stabilized by the addition of hydrochloric acid so that the concentration of the stored solution is approximately 1 mol/l.

5.2.1.7 Determination of the quantity of migrated elements

The methods specified in col 4 of Table 1 shall be used to determine their quantity.

5.2.1.8 Feeding bottle's components made of plastics, when tested in accordance with the method specified in col 4 of Table 1, shall not exceed the limits of elements as given in col 3 of Table 1.

Table 1 Permissible Levels of Heavy Metals in Plastic feeding bottle

(*Clause* 5.2.1.7)

Sl No.	Heavy Metals	Maximum Limit ppm Max	Ref to, IS No.
(1)	(2)	(3)	(4)
i)	Antimony	15	IS 15303
ii)	Arsenic	10	IS 3025 (Part 37)
iii)	Chromium	10	IS 3025 (Part 52)
iv)	Mercury	10	IS 3025 (Part 48)
v)	Cadmium	20	IS 3025 (Part 41)
vi)	Lead	25	IS 3025 (Part 47)
vii)	Barium	100	IS 1699
viii)	Selenium	100	IS 15303/IS 3025 (Part 56)

5.2.2 The limits and tolerances of the pigments and colourants used in the printing shall conform to IS 9833.

5.3 Performance Requirements

5.3.1 Environmental Stress-Crack Resistance

The bottles shall be tested in accordance with Method 1 of IS 8747 and shall show no evidence of stress cracking or leakage after being kept in oven for 48 h.

5.3.2 Transparency

The transparency of a plastics feeding bottle shall not be less than 70 percent in any light source transmittance when tested in accordance with the method described in Annex C.

5.3.3 Leakage Test

The bottles filled to brim level with water at ambient temperature and closed tight with closures shall be kept for 24 h in a horizontal position. During and at the end of the period, the bottles shall not show any leakages. The bottles shall be then held vertically upside down for 10 min and the bottle shall not show any leakages. The bottles may be kept on a blotting paper in upside down position and any leakages observed shall be noted.

5.3.4 *Drop Test*

The bottles filled to brim level with water at ambient conditions and closed tight with closures shall not show any sign of rupture or leakage when tested in accordance with the method described in Annex D. The dropping height of the bottles shall be 1.2 m.

5.3.5 Ageing Resistance

Immerse the bottles into the boiling water for 20 min, then immediately into the ice water for 20 min alternately and repeat it 3 times. At the end of the test, the change in the capacity of bottles shall not be more than 1 percent and also there shall be no defective changes in the bottle. There shall be no significant changes in appearance when the accessories are tested in accordance with the method indicated above.

5.3.6 Compressive Deformation Resistance

The bottles shall not get deformed by more than 10 percent in diameter in compressive direction at the compressive load of 2 kgf (19.6 N) when tested in accordance with the method described in Annex E.

5.3.7 Product Resistance of Printed Containers

The printed bottles when tested in accordance with the method prescribed in **14** of IS 2798 shall not show any significant removal of the print from the bottle surface and the print shall be legible to the naked eye after the test

5.3.8 *Migration Test*

Representative samples of feeding bottle shall be subjected to overall migration test either by filling the whole container or by using sheets cut from the container; in the latter case the migration value has to be extrapolated to the container contact surface area and the volume of the contents with the following:

- a) Distilled water at 40 ± 2 °C for 2h, and
- b) n-heptane at 38 ± 1 °C for 30 min.

The maximum extraction values for the container material shall not exceed 10 mg/dm² or 60 mg/l (for details of the test) (*see* IS 9845).

6 SAMPLE PREPARATION

The sample preparation applies to all tests except migration test given in **5.3.8.**

6.1 Samples from re-usable products shall be immersed in boiling water for 10 min without touching the walls of the container.

NOTE — This is to remove the surface coating arising from the manufacturing processes and ensure that the materials used are stable in boiling water.

- **6.2** New samples, preferably from the same batch, shall be used for each test.
- **6.3** Samples and test portions shall only be handled

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with suitable (non-rubber or plastic) gloves and shall only be stored in securely fastened, migration-free (glass) containers and protected from light.

7 PACKING AND MARKING

- **7.1** The bottles shall be packed as agreed to between the purchaser and the supplier.
- **7.2** Each bottle shall be permanently marked with scale mark.
- **7.2.1** Each carton containing the bottle shall be permanently marked with the following:
 - a) Indication of the source of manufacture and trade-mark, or the company responsible for placing the product in the market, if any;
 - b) Nominal capacity;
 - c) Batch No. and Code No.:
 - d) Month and year of manufacture;
 - e) Made from plastics materials meant for food contact applications indicating material used;
 - f) Product symbol in line with IS 14534; and
 - g) Instructions for use and hygienic care of the product shall be printed in English/Hindi/ regional language and may be included in a separate leaflet placed in or/on the product as given in 7.2.2.
- **7.2.2** *Instructions for Use*
- **7.2.2.1** The following information shall be provided:
 - a) Information for the safe use of the product;
 - Information on unsuitable common methods of heating which might damage the product.
- **7.2.2.2** For re-usable products the following additional instructions shall be provided:
 - a) At least one method of cleaning;
 - b) Before first use, clean the product; and
 - c) Information on unsuitable common methods

of cleaning, storage and use which might damage the product.

7.2.2.3 For products with feeding accessories the following 'WARNINGS' shall be provided in the form given:

For your child's safety and health

WARNING

- a) Always use this product with adult supervision.
- b) Always check food temperature before feeding.
- Keep all components not in use out of the reach of children.

NOTE — It is recommended that the supplier of drinking equipment include informative literature to explain the reasons and background for these warnings.

7.2.2.3 Heating in a microwave oven may produce localised high temperatures.

For products where microwave heating is recommended as a suitable method of food preparation the following instructions shall be provided although alternative wording is permitted:

Take extra care when microwave heating. Always stir heated food to ensure even heat distribution and test the temperature before serving.

7.3 BIS Certification Marking

The bottles may also be marked with the Standard Mark.

7.3.1 The use of the Standard Mark is governed by the provisions of *The Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

8 SAMPLING

The samples of the bottles shall be drawn and the criteria for conformity determined as prescribed in Annex F.

ANNEX A

(*Clause* 4.1)

LIST OF MATERIAL FOR MANUFACTURE OF PLASTIC FEEDING BOTTLES

(Based on Malaysian Standard, MS 735 and US FDA Regulations)

(1)(i) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

21 CFR 177.1520 (a)(3)(i)

Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of:

- (i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that:
 - (a) (1) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 or ethylene and octene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene;
 - (2) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 shall contain not less than 80 but not more than 90 weight percent of polymer units derived from ethylene.
 - (3) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and pentene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene.
 - (4) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1 shall contain not less than 50 weight-percent of polymer units derived from ethylene.
 - (b) Olefin basic copolymers manufactured by the catalytic copolymerization of

- ethylene and 4-methylpentene-1 shall contain not less than 89 weightpercent of polymer units derived from ethylene;
- (c) (1) Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4- trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene;
 - (2) Olefin basic copolymers manufactured by the catalytic copolymerization of propylene and butene-1 shall contain greater than 15 but not greater than 35 weight percent of polymer units derived from butene-1 with the remainder being propylene.
- (d) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, hexene-1, and either propylene or butene-1, shall contain not less than 85 weight percent polymer units derived from ethylene.
- (e) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1, or ethylene, octene-1, and either hexene-1, butene-1, propylene, or 4- methylpentene-1 shall contain not less than 80 weight percent of polymer units derived from ethylene.

21 CFR 177.1520 (b)

 (b) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4- methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;

21 CFR 177.1520 (c) Specifications

Item	Olefin polymers	Density	Melting Point (MP) or softening point (SP) in °C	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>n</i> - hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
(1)	(2)	(3)	(4)	(5)	(6)
1.1a 3.1a	Polypropylene described in paragraph $(a)(1)(i)$ of this section Olefin copolymers described in paragraph $(a)(3)(i)$ of this section for use in articles that contact food except for articles used for packing or holding food during cooking; except olefin copolymers described in paragraph $(a)(3)(i)(a)(3)$ of this section and listed in item $3.1c$ of this table and olefin copolymers described in paragraph $(a)(3)(i)(e)$ of this section and listed in item $3.1b$ of this table	0.85 – 1.00	MP: 160-180°C	6.4 percent at reflux temperature 5.5 percent at 50°C	9.8 percent at 25°C 30 percent at 25°C

ANNEX B

[Clause 5.1.4.2 (a)]

TEST FOR PERMANENCY OF PIGMENT

B-1 GENERAL

This test is meant only for those feeding bottles which have a printed scale and graduations.

B-2 REAGENTS

- **B-2.1 Sodium Bichromate,** see IS 249.
- **B-2.2** Concentrated Sulphuric Acid, relative density 1.834 approximately (*see* IS 266).

B-3 PROCEDURE

- **B-3.1** Weight about 20 g of sodium dichromate and dissolve in 1 500 ml of concentrated sulphuric acid and dilute to 2 500 ml with water. Immerse the bottles in the solution at room temperature for 15 min. Rinse the samples with water and dry.
- **B-3.1.1** The bottles shall be taken as having satisfied the requirements of the test, if the printed impressions do not become illegible.

ANNEX C

(*Clause* 5.3.2)

TRANSPARENCY TEST

C-1 GENERAL

Transparency of plastics feeding bottle can be tested either by using integration ball type light transmittance measurement apparatus or by method prescribed in ASTM 1003. In case of dispute, the test method given in ASTM 1003 shall be used as referee method.

C-2 INTEGRATION BALL TYPE LIGHT TRANSMITTANCE MEASUREMENT METHOD

C-2.1 Test Specimen

Test specimen shall be prepared from the part of feeding bottle where scale marks or other marks are not found.

C-2.2 Apparatus

The optical series principle diagram of integration ball type light transmittance measurement device is shown in Fig. 3 and Fig. 4. The device shall conform to the optical conditions specified in Table 2.

C-2.3 Test Specimen

The size of test specimen shall be 50×50 mm and the thickness shall be the original thickness of the test specimen.

Three test specimens shall be prepared.

C-2.4 Measurement

- **C-2.4.1** Install the white standard plate, adjust the reading (T_1) of the device's current meter to be 100; adjust the amount of incident light.
- **C-2.4.2** Under the status where the white standard plate is installed, install and measure the test specimen to obtain the indication (T_2) of the current meter. The full light transmittance shall be calculated according to the following formula:

where

T = full light transmittance, in percent.

Fig. 3 Principle Diagram of Device

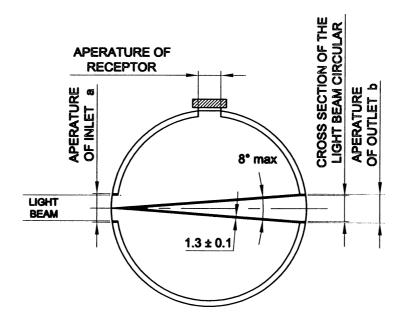


Fig. 4 Condition of the Integration Ball

Table 2 Optical Condition of Device

(Clause C-2.2)

Sl No.	Item	Conditions
(1)	(2)	(3)
(i)	Integration ball	The sum of areas of light's inlets and outlet (the installation part of the test specimens and the white standard plate) $(a+b+c)$ shall be less than 4 percent of overall internal surface are of the ball (<i>see</i> Fig. 2). The centre lines of the outlet and inlet shall be on the same large circle of the ball. The angle formed by the outlet diameter and the centre line of the inlet shall be within 8.
(ii)	Reflection surface	 a) The white standard plate shall have same high reflectivity to full wavelength of the visible light. Magnesium oxide, barium sulphate and aluminium oxide, etc, can meet such requirements. The interior of the integration ball shall be coated with a material having the same reflectivity as the white standard plate b) The light beams used to shine on the test specimen shall be parallel light. Lights deviated from the optical axis for more than 3° shall not be used. The centre of light beam shall coincide with the centre line of the outlet.
(iii)	Light beam	The cross-section of the light beam at the outlet shall be circular and bright; the angle formed by its diameter and the centre of inlet shall be $1.3 \pm 0.1^{\circ}$ smaller than the angle formed by the outlet diameter. The cross section of the light beam at the integration ball shall conform to Fig. 4.
(iv)	Light trap	The light trap when not installed with the test specimen of the white standard plate shall be able to completely absorb the light
(v)	Light source	a) The light source shall be the standard light source C.b) The comprehensive sensitivity of the receptor and the visually sensitivity filter used shall satisfy the Y value of Luther.
(vi)	Receptor	Conditions at the standard light source C. However, when designated specifically, the one which satisfies the Y value of Luther conditions at the standard light source A can be used.

ANNEX D

(*Clause* 5.3.4)

DROP TEST

D-1 SAMPLE SIZE

The sample size shall be ten bottles, taken at random from a batch, divided into two sets of 5 each, designate as Set 1 and Set 2.

D-2 PROCEDURE

D-2.1 Fill each bottle with water at ambient conditions and close tight with closures.

- **D-2.2** Drop the bottles under free fall conditions in Set 1 squarely on their base on to a rigid flat horizontal surface of steel of smooth concrete as the dropping surface.
- **D-2.3** Drop the bottles under free fall condition in Set 2 on their side (the body of the bottle being parallel to the impacting floor) onto the dropping surface.
- **D-2.4** Examine each bottle for signs of rupture or leakage.

ANNEX E

(*Clause* 5.3.6)

COMPRESSIVE DEFORMATION TEST

E-1 PROCEDURE

Apply the compressive load of 2 kgf in the middle part of the body or to the part having the maximum diameter of a feeding bottle by the use of compression jig as shown in Fig. 5 Measure the deflection of the part at that time, and calculate percentage deflection. The measurements shall be carried out at 27 ± 2 °C.

E-2 CALCULATION

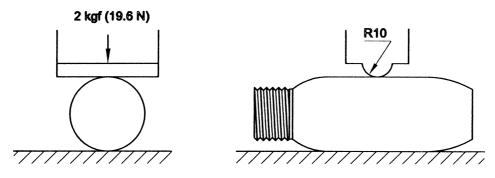


Fig. 5 Compression Jig

ANNEX F

(Clause 8)

SAMPLING OF PLASTIC FEEDING BOTTLES

F-1 SCALE OF SAMPLING

F-1.1 Lot

In any consignment, all the bottles of the same material, size and drawn from a single batch of manufacture shall be grouped together to constitute a lot.

F-1.2 Scale of Sampling

For ascertaining the conformity of the lot to the requirements of this standard, tests shall be carried out for each lot separately. The number of bottles to be sampled from a lot shall be in accordance with Table 3.

F-1.3 The bottles shall be selected at random from the lot. To ensure the randomness of selection, methods given in IS 4905 may be followed.

F-2 CRITERIA FOR CONFORMITY

F-2.1 Manufacture, Workmanship, Finish and Appearance

The sample bottles selected as per col 2 of Table 2 shall be examined for manufacture, workmanship, finish and appearance. Any bottle failing in one or more of the requirements shall be termed as defective. The lot shall be accepted under this head, if the number of defective bottles in sample does not exceed the acceptance number given in col 3 of Table 2.

F-2.2 Capacity (see also 5.1.4)

5 bottles for lot size up to 5 000 and 10 bottles for lot

size above 5 000 shall be selected at random from the samples already drawn according to **F-1.3**. There shall be no failure, if the lot is to be accepted under this clause.

F-2.3 Permanency of pigments (see 5.1.4.2), Transparency (see 5.3.2), Leakage test (see 5.3.3), Ageing resistance (see 5.3.5), Compressive deformation resistance (see 5.3.6), and ink adhesion for printed bottles (see 5.3.7). The number of sample bottles to be drawn shall be in according to col 4 of Table 2. Each of the sample bottles shall be subjected to Permanency of pigments (see **5.1.4.2**), Transparency (see 5.3.2), Leakage test (see 5.3.3), Ageing resistance (see 5.3.5), Compressive deformation resistance (see 5.3.6), and ink adhesion for printed bottles (see 5.3.7). The number of failures shall not exceed the acceptance number given in col 5 of Table 2 for all tests except leakage test. For leakage test the acceptance number is zero that is no failure shall occur for lot acceptance.

F-2.4 Drop Test (see also 5.3.4)

The sample bottles as given in test method (see 5.3.4) shall be drawn from the lot and these shall be subjected to drop test. There shall be no rupture or leakage in any bottle after the test for acceptance. In case even one bottle has any sign of rupture or leakage, the lot shall be considered as not conforming to the requirements of this specification.

Table 2 Scale of Sampling and Acceptance Number

(Clauses F-1.2, F-2.1 and F-2.3)

SI No.	Lot Size	Manufacture, Workmanship, Finish and Appearance		Ageing Resistance (Deformation R	3.2), Leakage Test (see 5.3.3), (see 5.3.5), Compressive esistance (see 5.3.6) Printed bottles (see 5.3.7)
(1)	(2)	Sample Size (3)	Acceptance Number (4)	Sample Size (5)	Acceptance Number (6)
i)	Up to 500	13	1	5	0
ii)	501 to 1 000	20	2	8	0
iii)	1 001 to 3 000	32	3	13	0
iv)	3 001 to 5 000	50	5	20	1
v)	5 001 and above	80	7	32	1

ANNEX G

(Foreword)

G-0 A scheme of labelling environment friendly products with the ECO logo has been introduced at the instance of the Ministry of Environment and Forests (MEF), Government of India. The ECO-Mark is being administered by the Bureau of Indian Standards (BIS) under The Bureau of Indian Standards Act, 1986 as per the Resolutions No. 71 dated 21 February 1991 and No. 425 dated 28 October 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with the ECO logo, it shall also carry the 1SI Mark of the BIS besides meeting additional environment friendly requirements. For this purpose the Standard Mark would be a single mark being a combination of the ISI mark and the ECO logo. This amendment is based on the gazette Notification No. 170 dated 18 May 1996 for plastic products as environment friendly products published in the Gazette of the Government of India.

G-1 ADDITIONAL REQUIREMENTS FOR ECO-MARK

G-1.1 General Requirements

- **G-1.1.1** The product shall conform to the requirements for quality, safety and performance prescribed in this Indian Standard.
- **G-1.1.2** The manufacturer shall produce to BIS the consent clearance as per the provisions of *The Water (Prevention & Control of Pollution) Act*, 1974 and *The Air (Prevention & Control of Pollution) Act*, 1981 along

with the authorization, if required under *The Environment (Protection) Act*, 1986 and the rules made thereunder while applying for the ECO-Mark. The manufacturer shall produce documentary evidence with respect to the compliance of regulation under *The Prevention of Food Adulteration Act*, 1954 and *The Drugs and Cosmetic Act*, 1940 and Rules made thereunder, wherever necessary.

- **G-1.1.3** The product must display a list of critical ingredients in descending order of quantity present expressed as percent of the total. The list of such ingredients shall be identified by Bureau of Indian Standards.
- **G-1.1.4** The product packaging shall display in brief the criteria based on which the product has been labelled as 'Environment Friendly'.
- **G-1.1.5** The material used for product packaging shall be recyclable or biodegradable.
- **G-1.1.6** It shall also suitably mention that ECO-Mark label is applicable only to the packaging material/package, if content is not separately covered under ECO-Mark. It may be stated that ECO-Mark is applicable to the product or packaging material or both.

G-1.2 Product Specific Requirements

For the manufacture of this product, one or more of the virgin material as given in 4 shall be used.

(Continued from Second cover)

EEC Directives Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles

JIS T 9112: 1997 'Feeding bottles', issued by Japanese Standards Association, Japan

The general information regarding ECO-Mark is given in Annex G.

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 'Rules for rounding off numerical values (*revised*)'.

Bureau of Indian Standards

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Amendments Issued Since Publication

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