

Specification for

Babies' elastomeric feeding bottle teats

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Consumer and Contract Goods Standards Policy Committee (CCM/-) to Technical Committee CCM/42, upon which the following bodies were represented:

Association for Consumer Research (ACRE)
 Association of Public Analysts
 British Paediatric Association
 British Retailers' Association
 British Rubber Manufacturers' Association
 Child Accident Prevention Trust
 Consumer Policy Committee of BSI
 Department of Health
 Department of Trade and Industry (Laboratory of the Government Chemist)
 Department of Trade and Industry (Consumer Safety Unit, CA Division)
 Health Visitors' Association
 Ice (Ergonomics)
 Infant and Dietetic Foods Association
 Institute of Trading Standards Administration
 Malaysian Rubber Producers' Research Association
 Royal College of Nursing
 Royal Society for the Prevention of Accidents
 Society of Public Health

This British Standard, having been prepared under the direction of the Consumer and Contract Goods Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 30 September 1990

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The following BSI references relate to the work on this standard:
 Committee reference CCM/42
 Draft for comment 89/47216 DC

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Amendments issued since publication

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Foreword

This British Standard has been prepared under the direction of the Consumer and Contract Goods Standards Policy Committee. Where appropriate, relevant sections of BS 5239 have been adopted, viz. requirements for resistance to bite and for the limitation of the presence of nitrosamines. Requirements for puncture and tear resistance were considered inappropriate for feeding teats which are for use with adult supervision and not designed to take the place of a dummy. Requirements for maximum permissible levels of certain soluble metals or their compounds have been aligned with those in BS 5665-3 which is identical to Part 3 of the European Standard EN 71. The presence of undesirable plasticizers in plastics has been considered but at present there is insufficient information available on the toxicity of many plasticizers or test methods for their determination. When more information is available on this subject it will be reconsidered.

Manufacturers should refer to the Materials and Articles in Contact with Food Regulations, Statutory Instrument 1987 No. 1523 and all subsequent amendments and to the European Commission Directive "Plastics materials & articles intended to come into contact with foodstuffs", 90/128/EEC and all subsequent amendments.

The Technical Committee responsible considered the possibility of standardizing ranges of teat flow rate but decided that present laboratory methods of test for the determination of flow rate were of no real value since the sucking action of infants, which varied considerably, changes the shape of the feed aperture. The sucking action and change in aperture shape had an even greater effect on flow than other factors such as teat design, shape of hole, viz. circular or slit, material of construction, viscosity of bottle contents, etc. A given teat may provide a high flow rate for an infant that sucks strongly and a low flow rate for an infant that sucks poorly.

It is recommended that the manufacturing process, packaging, storage and transportation of single use sterilized teats should be in accordance with the "Guide to good manufacturing practice for sterile medical devices and surgical products" HMSO, 1981.

Design guidance to improve the instructions that accompany consumer products is given in "Instructions for consumer products" HMSO, 1988.

WARNING. Infants must not be bottle fed without adult supervision.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 4, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This British Standard specifies requirements for materials, design, performance, packaging and marking for elastomeric teats for babies' feeding bottles which are not cleft lip or cleft palate teats. It includes methods of test for those requirements and also recommendations for the use and care of feed teats.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this British Standard the following definition applies.

teat

a substitute nipple that when attached to a container holding a fluid permits a baby to obtain the fluid from the container by sucking

3 Materials

3.1 The nipple and body of teats shall be made entirely of elastomeric materials, see 4.7.

NOTE Feed teats should be manufactured in such a way that the use of the teat will not be injurious to health or cause mucosal irritation by reason of any leachable constituents from the teat or of any substance remaining on the surface of the finished product after washing.

3.2 Feed teats shall meet the migration requirements of BS 5665-3 and shall not contain in excess of 30 $\mu\text{g}/\text{kg}$ total volatile nitrosamine content, neither shall they contain in excess of 15 $\mu\text{g}/\text{kg}$ of any one volatile nitrosamine, when determined in accordance with BS 7115-1.

NOTE The maximum permissible levels of nitrosamines have been set taking into account the variability of test results between laboratories.

4 Requirements for individual features

4.1 Designation of individual features

For the purposes of this British Standard the features of a teat shall be designated as shown in Figure 1.

4.2 Construction

If two or more component parts are used in the construction of a teat the component parts shall be joined permanently together.

NOTE Compliance with this requirement is established by the test procedure and requirements of 5.1.

4.3 Feed aperture(s)

Feed aperture(s) shall be located on the nipple.

4.4 Vent hole(s)

Vent holes, if present, shall be located in the lower section of the body or in the flange.

4.5 Surface finish

Both inner and outer surfaces of the teat shall be smooth. With the exception of the feed aperture(s) and vent holes the teat shall be free from other holes and free from defects, e.g. cracks, pits and moulding flash that could impair performance, for example in use.

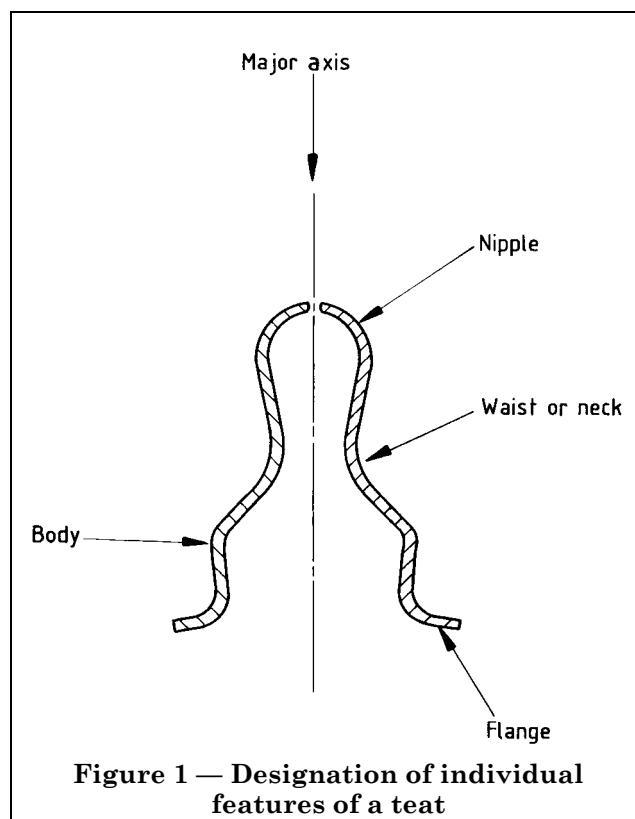
4.6 Cleanliness under use

Re-usable teats shall allow full visual inspection, and cleaning of the inner surface, either by deformation or by turning inside out, if appropriate.

NOTE If it is inappropriate to turn inside out this should be stated in the marking [see 7.1 e)].

4.7 Elasticity

The teat shall have sufficient elasticity so that after deformation, such that the inner surfaces of the nipple are in contact, it regains its original shape.



5 Performance of the teat

5.1 Tensile strength

When tested in accordance with **A.2** the teat shall remain intact.

5.2 Bite resistance

When tested in accordance with **A.3** the teat shall exhibit no permanent damage that would render it unusable or unsafe.

6 Packaging

6.1 Re-usable teats

Teats shall be packed in a clean condition and supplied to the consumer in closed packs. Each pack shall contain not more than six feeding teats.

NOTE This is to reduce the possibility of teats being separated from information marked on, or enclosed in, each pack

6.2 Single use, disposable teats, supplied sterilized ready for use

Each teat shall be packed in a clean condition in a closed unit. Each unit shall contain a single feeding teat. The maximum number of units incorporated into a pack shall be 10.

NOTE 1 IMPORTANT. It is imperative that closed units are sterilized and that the packaging serves as a microbiological barrier and is sufficiently robust to maintain the sterility of the contents under conditions of handling and storage normally encountered.

NOTE 2 It is recommended that the manufacturing process, packaging, storage and transportation of single use sterilized teats should be in accordance with the "Guide to good manufacturing practice for sterile medical devices and surgical products", HMSO, 1981.

7 Marking

7.1 Re-usable teats

When supplied to the consumer the following information shall be legibly marked on each pack or enclosed in each pack:

- a) the number and date of this British Standard, i.e. BS 7368:1990¹⁾;
- b) the name, trademark or other means of identification and the address in the UK of the manufacturer, distributor or retailer;

c) the following instructions in English:

“WARNING

Inspect immediately before and after each use and throw away when worn, damaged or punctured, for example by biting.

Before use, wash thoroughly and sterilize. Always wash immediately after use. Keep in a dry, covered container. Do not leave in sunlight when not in use. **INFANTS MUST NOT BE BOTTLE FED WITHOUT ADULT SUPERVISION.** Feeding teats should not be used as dummies/pacifiers/soothers.”;

d) instructions on sterilization;

e) if it is inappropriate to turn the teat inside out for inspection and cleaning a statement to this effect.

If any substance in common household use, likely to come into contact with the teat, is known to have an adverse effect on the materials of the teat, then each pack shall carry a warning that contact with that substance should be avoided.

7.2 Single use, disposable teats, supplied sterilized ready for use

Each pack (see **6.2**) shall carry the following information in a legible form:

- a) the information in items a) and b) of **7.1**;
- b) the following instructions in English;

“WARNING

Inspect immediately before use and throw away if the pack or its contents are damaged.

Do not leave in sunlight prior to use. **INFANTS MUST NOT BE BOTTLE FED WITHOUT ADULT SUPERVISION.** Feeding teats should not be used as dummies/pacifiers/soothers. Use once only. Do not re-use.”;

c) the word “sterilized”.

¹⁾ Marking BS 7368:1990 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is therefore solely the responsibility of the person making the claim. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

Appendix A Methods of test for performance of the teat

A.1 General

A.1.1 Tests shall be conducted at room temperature.

A.1.2 For third party certification purposes and for verification of a manufacturer's claim that his product conforms to BS 7368:1990, the cross-head speed given in **A.2** and **A.3** shall be used.

Alternative manual or mechanical procedures could be used in other situations applying the load gradually over a period of 5 s.

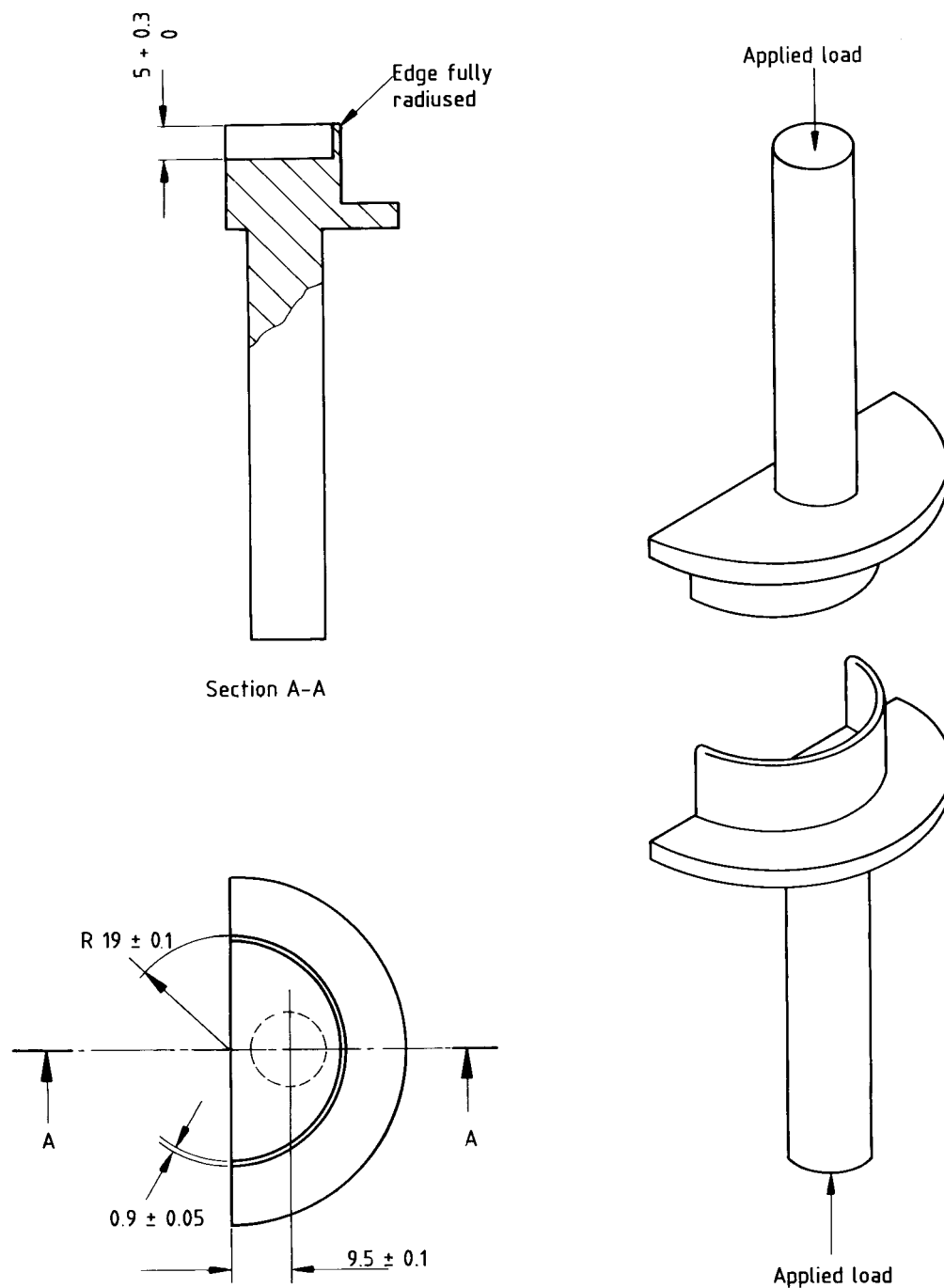
A.2 Tensile strength test

Compress opposite sides of the flange together and clamp, perpendicular to the major axis, 10 ± 2 mm of the compressed edges of the flange together using a suitable fixture. Hold, perpendicular to the major axis, 10 ± 2 mm of the tip of the nipple in a suitable fixture and apply a tensile force of 90 ± 3 N to the nipple along the major axis of the teat at a cross-head speed of 195 mm/min to 255 mm/min. Apply the full load for 10 ± 0.5 s.

A.3 Bite test

Using the test jaws shown in Figure 2, with the nipple section of the teat between the jaws apply a force of 220 ± 5 N to the jaws at a cross-head speed of 195 mm/min to 255 mm/min. Apply full load for 10 ± 0.5 s.

NOTE Make sure the machine is capable of stopping at 220 ± 5 N when using a cross-head speed of 195 mm/min to 255 mm/min or damage to the load cell will result. It is possible to use a machine to lower a mass equivalent to 220 N onto the jaw to prevent the load cell from being subjected to a force greater than 220 N.



All dimensions are in millimetres.

Figure 2 — Jaws for bite test

Publication(s) referred to

BS 5239, *Specification for babies' dummies.*

BS 5665, *Safety of toys.*

BS 5665-3, *Specification for migration of certain elements.*

BS 7115, *Determination of volatile nitrosamines in rubber teats for feeding bottles and babies' dummies.*

BS 7115-1, *Dichloromethane extraction method.*

EN 71, *Safety of toys*²⁾.

EN 71-3, *Requirements for the migration of certain elements.*

Guide to good manufacturing practice for sterile medical devices and surgical products, HMSO, 1981
Instructions for consumer products, HMSO, 1988²⁾.

²⁾ Referred to in the foreword only.

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