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DRAFT EAST AFRICAN STANDARD

Baby pacifier/soother — Specification

EAST AFRICAN COMMUNITY

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Copyright notice

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 072, *Plastics and related products*.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

Baby pacifier/soother — Specification

1 Scope

This Draft East Africa Standard specifies requirements, sampling and test methods for baby pacifiers/soothers.

This standard is not applicable to fruit pacifier.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 1086, *Plastics Codes for resin identification on plastic products*

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:

— IEC Electropedia: available at http://www.electropedia.org/

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

3.1
baby pacifier/soother
device used to meet children's non-nutritive sucking needs consisting of a nipple that is intended for a young child to suck or bite upon, but is not designed to facilitate a baby's obtaining of fluid, and usually includes a guard and a handle or ring

3.2
nipple/teat
soft part of the pacifier that is to be placed in the mouth of a child

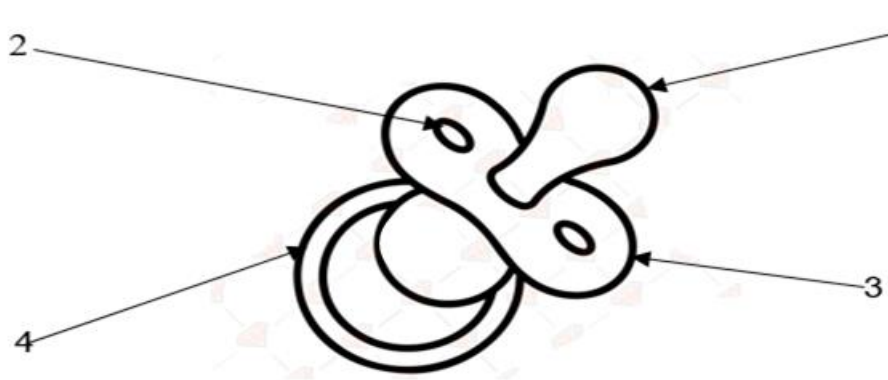
3.3
ring or handle
a component or part attached that facilitates for easy holding/grasping of the pacifier

3.4
ventilation hole
hole on the guard of the pacifier that provides an air passage for children to breathe

3.5
guard
means the structure located at the base of the nipple used to prevent the pacifier from being completely drawn into the child's mouth

4 Description

The structure of the pacifier is given in figures 1 and 2.



Key

1 Nipple/teat

2 Ventilation hole

3 Guard

4 Ring/handle

Figure 1 — Basic parts of pacifier

5 Requirements

5.1 General requirements

5.1.1 All materials used in the manufacture of the baby pacifier/soother shall be virgin food grade.

5.1.2 Baby pacifier/ soother with loose parts that can produce a rattle effect shall be in-built and these shall not appear on the nipple tip.

5.1.3 Baby pacifier/ soother shall not have any sharp points or sharp edges and shall not have removable parts.

5.1.4 Baby pacifier/ soother shall not have any ribbon, string, cord, chain, twine, leather, yarn or any similar attachments.

5.1.5 Manufacturers should ensure the use of recyclable or biodegradable materials in pacifiers to minimize environmental impact, in accordance with ISO 14001.

5.1.4 Handles

5.1.4.1 Hard handles, plugs or covers protruding from behind the guard, the protrusion distance shall not be less than 10 mm and not more than 16 mm

5.1.4.2 The assembled pacifier handle shall be easy to hold as possible, so that it can be easily removed from the child's mouth

5.1.5 Nipple

5.1.5.1 The hollow part of the nipple shall not contain solid, liquid or gaseous substances (except air), the nipple shall not contain any foreign substance.

5.1.5.2 The nipple head or the sucking surface shall not have any holes and shall be smooth.

5.1.5.3 The maximum length of the nipple measured from the guard shall be 35 mm.

5.1.6 Guard

The guard shall contain at least two holes symmetrically located and each being at least 5 mm in minor dimension. The edge of any hole shall be no closer than 5 mm to the perimeter of the pacifier guard.

5.1.7 Imprinting and decorations

Baby pacifier/soother shall be free from any ink-based designs, prints, or markings. Any ink-based designs, decorations, or imprints may be made on the primary packaging of the baby pacifier/soother.

5.2 Specific requirements

The pacifier/baby soother shall conform to the specific requirements specified in Table 1 when tested in accordance with the test methods prescribed therein.

Table 1 – Requirements for the tests

S.N	Parameter	Requirement	Test method
i.	Impact resistance	The pacifier parts shall not rupture, tear, or separate	Annex A
ii.	Structural integrity tests		
iii.	Puncture resistance, N, min	30	Annex B,
iv.	Tear resistance	The nipple tip and handle shall not be broken or separated	Annex C
v.	N-nitrosamines, mg/kg, max	0.01	Annex D
vi.	N-nitrosatable, mg/kg, max	0.1	
vii.	Temperature resistance	The pacifier shall not crack or tear	Annex E

6 Packaging

6.1 The pacifier/ baby soother shall be suitably packed in retail cartons containing two or more pacifiers or individually packaged to guarantee product integrity during transportation, storage, and handling.

6.2 Packaging should be done in accordance with ISO 18601.

7 Labelling

7.1 Retail display carton containing two or more pacifiers shall be labelled with the statement: ‘‘Warning— Do not tie pacifier around child’s neck as it presents a strangulation danger.’’

7.2 The pacifier packaging material shall be labelled with the following information:

a) name of product as “pacifier”;

b) name of the manufacturer and/or trademark;

c) code of resin identification and symbol for recycling in accordance with EAS 1086;

d) instruction for use, hygienic care, disposal;

e) caution/warnings including that prescribed in 7.1;

f) number of pacifiers in each package;

g) batch number;

h) month and year of manufacture; and

i) date of expiry since rubber expires.

Annex A
(normative)

Impact resistance test/structural integrity tests

A.1 Impact resistance test

A.1.1 Procedure

A.1.1.1 Place the pacifier on a clean flat horizontal steel surface. The pacifier should be tested in an unsupported state.

A.1.1.2 Drop a flat stainless-steel metal of 10 kg ± 2 kg and diameter 80 mm ± 2 mm from a height of 100 mm ± 2 mm from the nipple so that the center of the weight comes into contact with the nipple. This is carried out with the same pacifier five times; each impact test corresponds to a different placement on the nipple.

A.1.1.3 Average the quality of a piece distributed in diameter 80 mm ± 2 mm on the nipple.

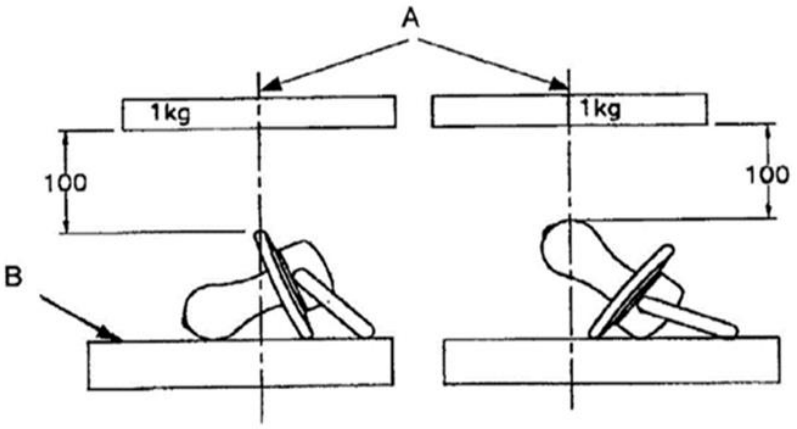


Figure A.1 — Schematic diagram of the impact resistance test position of the pacifier

A.2 Structural integrity tests

A.2.1 General

A.2.1.1 Structural integrity tests shall be done on a baby pacifier/soother that has passed the impact resistance test.

A.2.1.2 During testing, the force shall be applied along the major axis of the pacifier.

A.2.1.3 For pacifiers with a ring, apply force between the ring and the nipple tip.

A.2.1.4 For pacifiers with graspable handles, apply force between the handle and the nipple tip.

A.2.1.5 For plugs, caps, or handles that cannot be clamped, apply force between the guard and the nipple tip.

A.2.2 Procedure

The following method is to be used for testing the structural integrity of the pacifier:

a) hold the nipple of the pacifier in a fixed position and apply to the ring or handle of the pacifier a force of 44,5 N ± 1,0 N in the plane of the axis of the nipple at a rate of 4,5 N/s ± 1,0 N/s. After attaining the final force of 44,5 N ± 1,0 N, maintain it for 10,0 s ± 0.5 s;

b) hold the guard of the pacifier in a fixed position and apply to the ring or handle of the pacifier a force of 44,5 N ± 1,0 N in the plane perpendicular to the axis of the nipple at a rate of 4.5 N/s ± 1.0 N/s and then maintain the final force for 10,0 s ± 0.5 s;

c) hold the guard of the pacifier in a fixed position and apply to the nipple a force of 44,5 N ± 1,0 N in the plane perpendicular to the axis of the nipple at a rate of 4.5 N/s ± 1.0 N/s and then maintain the final force for 10,0 s ± 0.5 s;

Annex B
(normative)

Puncture resistance test of the nipple tip

B.1 From a complete pacifier cut the nipple head as close as possible to the guard.

B.2 Place the nipple head on a flat hard cutting surface.

B.3 A 3 mm Knife edge cutter (shape and size are shown in the Figure B.1 is placed directly above the cutting edge away from the nipple 5 mm ± 0.5 mm.

B.4 Align the major axis of the nipple head vertically, when the nipple head does not have a circular cut surface, the cutter should be placed on the flat surface of the nipple head and neck.

B.5 Apply the load at a controlled speed of 100 mm/min until the cutter completely cuts through the upper surface of the nipple head. Use a universal tester to apply force. Make sure the force is applied vertically.

NOTE Before use, the cutting edge of the cutter should be inspected visually. If any damages like burrs or chipping are found, then this cutter cannot be used to avoid affecting the test results.

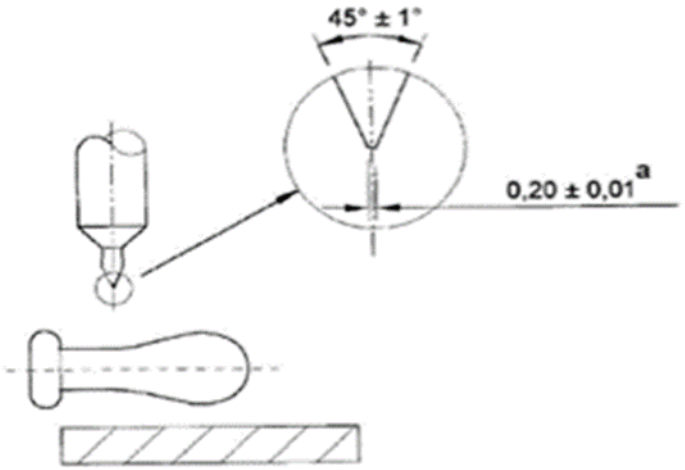


Figure B.1 – Schematic diagram of the location of the puncture resistance test of the pacifier

Annex C
(normative)

Tear resistance test of the nipple tip

C.1 Tested with a brand-new pacifier, using a 3 mm knife edge cutter (shape and size are shown in Figure C.1.

C.2 Place the nipple head 7.5 mm ± 0.5 mm above the cutting edge, align with the major axis of the nipple tip at an appropriate angle.

C.3 Apply pressure to ensure that the cutter cuts through the two surfaces of the nipple head and cuts into the cutting plate approximately 1 mm.

C.4 After the test, the pacifier shall be tested for tensile strength by clamping the guard with a suitable appliance, the guard shall be fixed so that the opening caused by the cutter faces upwards.

C.5 A force of 10 N ± 5 N shall be applied on the axis of the nipple.

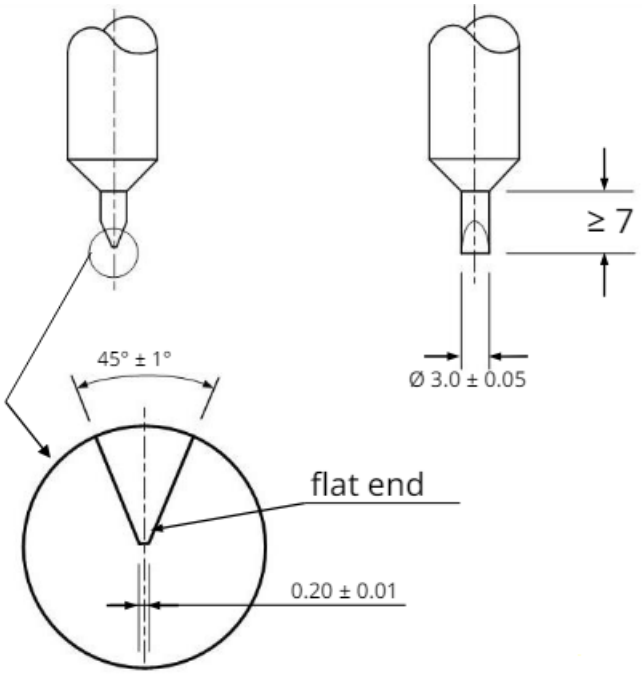


Figure C.1 — Schematic diagram of the knife edge cutter

Annex D
(normative)

Determination of N-nitrosamines and N-nitrosatable content

D.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 ($NaNO_2$) in one litre of distilled water or water of equivalent quality. The solution must have a pH value of 9 0.

D.2 Test conditions

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

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

D.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.

D.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 E
(normative)

Temperature resistance test

E.1 The pacifier shall be submerged in boiling water for 5 minutes and then removed and allowed to cool to room temperature.

E.2 The procedure E.1 shall be repeated 5 more times for a total of 6 boiling/cooling cycles.

E.3 After the 6 boiling/cooling cycles, the tests below shall be performed on the pacifier;

a) hold the nipple of the pacifier in a fixed position and apply to the ring or handle of the pacifier a force of 44,5 N ± 1,0 N in the plane of the axis of the nipple at a rate of 4,5 N/s ± 1,0 N/s. After attaining the final force of 44,5 N ± 1,0 N, maintain it for 10,0 s ± 0.5 s;

b) hold the guard of the pacifier in a fixed position and apply to the ring or handle of the pacifier a force of 44,5 N ± 1,0 N in the plane perpendicular to the axis of the nipple at a rate of 4.5 N/s ± 1.0 N/s and then maintain the final force for 10,0 s ± 0.5 s;

c) hold the guard of the pacifier in a fixed position and apply to the nipple a force of 44,5 N ± 1,0 N in the plane perpendicular to the axis of the nipple at a rate of 4.5 N/s ± 1.0 N/s and then maintain the final force for 10,0 s ± 0.5 s;

Bibliography

[1] *Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers*

[2] 16 CFR Part 1511 — *Requirements for pacifiers*, 2012

[3] *Pacifiers Regulations*, SOR/2016-184, July 25, 2023

[4] TIS 1025-2562

