Child use and care articles — Soothers for babies and young children —

Part 2: Mechanical requirements and tests

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National foreword


The UK participation in its preparation was entrusted to Technical Committee CW/42, Babies soothers, soother holders and feeding equipment, which has the responsibility to:

— aid enquirers to understand the text;
— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 26, an inside back cover and a back cover.

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Child use and care articles - Soothers for babies and young children - Part 2 : Mechanical requirements and tests

This European Standard was approved by CEN on 28 July 2002.

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Foreword

This document EN 1400-2:2002 has been prepared by Technical Committee CEN/TC 252 "Child use and care articles", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This European Standard 1400 “Child use and care articles – Soothers for babies and young children” consists of the following parts:

— Part 1: General safety requirements and product information
— Part 2: Mechanical requirements and tests
— Part 3: Chemical requirements and tests

This part of this European Standard contains two annexes:

- annex A (informative) Some examples of suitable fixing devices
- annex B (informative) Soothers - Assessment of compliance with standard - Sampling plan and compliance levels for freshly manufactured samples

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.
Introduction

Soothers are widely used throughout Europe to satisfy non nutritive-sucking needs and to pacify children.

They are designed to be in the mouths of babies and young children for long periods. Accidents, some of which have been fatal, have occurred in the past and a prime purpose of this standard is to reduce the risk of accidents occurring in the future. It is stressed that this European Standard cannot eliminate all possible risks to babies and young children using such a product and that parental or guardian control is of paramount importance. It is essential that all warnings and instructions specified in this standard are given clearly by the manufacturer, to allow the consumer to ensure that the soother is used correctly and safely.

This European Standard for soothers for babies and young children consists of the following parts:

- **Part 1:** General safety requirements and product information
- **Part 2:** Mechanical requirements and tests
- **Part 3:** Chemical requirements and tests

The complete European Standard harmonises for the first time minimum safety requirements and test methods for soothers. Most of the provisions have been taken from other existing national and European Standards and for these provisions the Technical Committee has relied on previous validation.

It is not permitted to claim compliance with individual parts of this standard. Any claim relates to all published parts.

It is recommended that manufacturers and suppliers operate to EN ISO 9000 series standards for quality management systems.

In addition it is recognised that some organisations require reference testing. A suggested sampling plan and compliance levels for freshly manufactured soothers are provided in annex B (informative). This procedure can be used as a voluntary type approval procedure.

Some concern was expressed regarding the softness of the soother teat. However as no approved testing method was found, it was decided to consider this aspect at the time of revision of this standard.
1 Scope

This part of this European Standard specifies mechanical requirements and test methods for the performance of soothers for babies and young children.

This European Standard is applicable to products that resemble or function as a soother unless they are being marketed as medical devices.

This European Standard does not apply to products designed for specialist medical applications, e.g., those relating to Pierre-Robin Syndrome or premature babies. These special cases are described in an informative annex (see EN 1400-1:2002, annex A).

NOTE It is recommended that soothers excluded from the scope of this European Standard should meet those requirements that can be applied.

The standard is not applicable to feeding teats. 1

2 Normative references

This European Standard incorporates, by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 1400-1, Child use and care articles - Soothers for babies and young children - Part 1: General safety requirements and product information.

EN 1400-3, Child use and care articles - Soothers for babies and young children - Part 3: Chemical requirements and tests.


ISO 188, Rubber, vulcanized or thermoplastic - Accelerated ageing or heat-resistance tests.


ISO 291, Plastics - Standard atmospheres for conditioning and testing.

ISO 2859-1, Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

3 Terms and definitions

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

3.1 soother
article intended for satisfying the non-nutritive sucking need of children

1 A standard for safety requirements and test methods for drinking equipment is in preparation.
NOTE Soothers are also known as pacifiers or babies’ dummies.

3.2
**teat**
flexible nipple which is the part of the soother designed to be placed in the mouth

3.3
**shield**
structure positioned at the rear of the teat to reduce the likelihood of the soother being drawn entirely into the child’s mouth

3.4
**ring or knob**
structure positioned adjacent to or on the shield to facilitate handling of the soother

NOTE The ring, knob or cover can be integral with the shield or plug or it can be a separate component that is attached to the shield or plug.

3.5
**plug**
device located within the neck of the teat that secures the teat to the shield

3.6
**cover**
device that prevents open access to the plug

3.7
**ventilation holes**
holes in the shield of a soother which provide an air passage through which a child can breath, should the soother become accidentally lodged in the mouth. The holes also reduce the risk of the soother being sucked into the pharynx through the generation of negative pressure
4 Description of a soother

A soother as shown in Figures 1, 2, 3 and 4 can consist of:

a) teat (1)  
b) shield (2)  
c) ring (3)  
d) plug (4)  
e) cover (5)  
f) knob (6)

NOTE Similar components are marked with the same number in Figures 1 to 4.

Key

1 Teat  
2 Shield  
3 Ring  
4 Plug  
5 Cover  
7 Sucking face of shield

Figure 1 – Example of a soother with ring
Figure 2 – Example of a soother with knob

Key

1 Teat
2 Shield
4 Plug
6 Knob
Key

1 Teat
2 Shield
4 Plug
5 Cover
7 Sucking face of shield

Figure 3 – Example of a soother with plug and cover
5 Performance of the soother

5.1 Impact resistance

The soother shall be tested as described in 6.2.1 and no part shall break, tear or separate during this test or the tensile strength test described in 6.2.7.1.

5.2 Puncture resistance

The soother shall be tested as described in 6.2.2. When tested for puncture resistance as described in 6.2.2.1, the load to cut completely through one wall of the teat shall be greater than 30 N.

If the soother is fitted with a flexible knob, when tested for puncture resistance as described in 6.2.2.2, the load to cut completely through one wall of the knob shall be greater than 30 N.
5.3 Tear resistance

The soother shall be tested as described in 6.2.3. When tested for tear resistance as described in 6.2.3.1, the teat shall not break or separate during the tensile strength test.

If the soother is fitted with a flexible knob, when tested for tear resistance as described in 6.2.3.2, the knob shall not break or separate during the tensile strength test.

5.4 Knob, plug and/or cover retention

The soother shall be tested as described in 6.2.4 and no part shall break or separate to become an accessible part.

5.5 Biting endurance

The teat and soft flexible knobs of the soother shall be tested as described in 6.2.5 and no part shall break, tear or separate during this test or tensile strength test as described in 6.2.7.1. If the design of the soother makes it impossible to apply a tensile force to the two sides of the biting surface on the flexible material, then the material shall not exhibit either any evidence of being cut or any separation between flexible and rigid parts of the soother. Marks, confined to the surface of the flexible material, shall be ignored.

5.6 Rotation endurance

Soothers incorporating any part capable of being rotated (360°) within the teat of the soother when a torque of (1 ± 0.2) Nm is applied, shall be tested as described in 6.2.6 and the teat shall not tear or separate during this test or tensile strength test as described in 6.2.7.1.

5.7 Integrity

Additional tests shall be carried out to ensure the integrity of all components not already examined as part of 6.2.1 to 6.2.6.

The soother shall be tested as described in 6.2.7.2 and no part shall break, tear or separate during the test.
6 Testing

Samples taken direct from manufacturer prior to being placed on the market

All other samples

6.1.1 Pretreatment

6.1.3 Conditioning

6.1.2 Boiling

6.1.3 Conditioning

6.1.4 A sample used in any of the tests below shall not be used in any further tests

All soothers

6.2.1 Impact resistance test

Followed by

6.2.2.1 Puncture resistance test of teat

6.2.3.1 Tear resistance test of teat

Followed by

6.2.7.1 Tensile test at right angles to the major axis (see Figure A.2)

6.2.4 Knob, plug and/or cover retention test

Followed by

6.2.5 Biting endurance test

Followed by

6.2.7.1 Tensile test at right angles to the major axis (see Figure A.2)

6.2.7.2 Additional tests

Additional tests for soothers with flexible knobs

6.2.2.2 Puncture resistance test of flexible knob

6.2.3.2 Tear resistance test of flexible knob

Followed by

6.2.7.1 Tensile test at right angles to the major axis (see Figure A.2)

6.2.5.3 Biting endurance procedure for soft flexible knobs

Followed by

6.2.7.1 Tensile test at right angles to the major axis (see Figure A.2)

Additional tests for soothers where a part rotates inside the teat (See 5.6)

6.2.6 Rotation endurance test

Followed by

6.2.7.1 Tensile test along the major axis (see Figure A.1)

Figure 5 – Testing scheme for mechanical properties
6.1 Preparation of samples and general testing methods for oven treatment

6.1.1 Only samples taken directly from the manufacturer prior to being placed on the market shall be artificially aged for 7 days in an aerated drying cabinet at a temperature of \((70 \pm 2) ^\circ C\) (as described in ISO 188) and conditioned as described in 6.1.3. Samples shall then be boiled as described in 6.1.2 and again conditioned as described in 6.1.3.

6.1.2 All samples shall be immersed in boiling water, to the requirements of EN ISO 3696, Grade 3, for 10 min without touching the walls of the container and then conditioned as described in 6.1.3 (this is to remove the surface coating due to manufacturing processes and to ensure that the construction and materials used are stable in boiling water).

6.1.3 All samples shall be conditioned before the tests. The conditioning of the samples shall be performed for at least 40 h in a standard atmosphere in accordance with ISO 291: temperature \((23 \pm 2) ^\circ C\), and relative humidity \((50 \pm 5) \%\). Samples shall remain in the conditioning atmosphere until the test is carried out. The tests can be carried out in a non-conditioned room.

6.1.4 New samples shall be used for each test (i.e. samples used in one test shall not be used in another test) or for each testing orientation, unless otherwise stated.

6.2 Test methods

6.2.1 Impact resistance test

Place the soother to be tested unsupported on a flat, horizontal steel surface. Drop a flat metal weight with a mass of \((1 \pm 0.02) \text{ kg}\), distributed over an area of diameter \((80 \pm 2) \text{ mm}\), from a height of \((100 \pm 2) \text{ mm}\) above the highest point of the soother so that the centre of the weight is the first point to contact the soother. The test shall be carried out 5 times on the same sample with as far as is practical, each impact carried out with the soother in a different stable orientation (see Figure 6).

After this treatment the soother shall be tested for tensile strength according to 6.2.7.1, along the major axis of the soother. For a soother with a ring, apply the force between the ring and the teat. For a soother with a knob which can be gripped, the force shall be applied between the knob and the teat. For a soother with a plug, cover or knob, which can not be held by a fixture device, the force shall be applied between the shield and the teat.

Figure 6 – Examples of positions of the soother for the impact test
6.2.2 Puncture resistance test

6.2.2.1 Puncture resistance test of teat

Cut the teat from the complete soother as close as possible to the shield and place the teat on a cutting board at least 10 mm thick, (70 ± 5) Shore D hardness (see Figure 7).

NOTE 1 This Shore Hardness is equivalent to 97 IRHDs.

NOTE 2 Collaborative studies have shown it to be preferable to test separated components of the complete soother to achieve suitable repeatability and reproducibility.

Dimensions in millimetres

![Diagram of puncture resistance test setup]

Figure 7 - Example of position of the soother teat for puncture resistance test

Place the indentor, the shape and dimensions of which are given in Figure 8, with the 3 mm edge of the indentor centred over and at right angles to the major axis of the teat and (5 ± 0.5) mm from the cut edge of the teat.

In the case of teats not having a circular cross section, the indentor shall be positioned over the flattened surface of the neck of the teat.

At a cross-head speed of (10 ± 1) mm/min apply a load until the indentor cuts completely through the upper wall of the teat.

The force shall be applied by using a universal-testing machine. This ensures that the force is applied vertically.

NOTE 3 Before use, the tip of the indentor should be inspected visually. If any damage such as burrs or chips, is observed, the indentor should not be used to avoid effecting the results of the test.
6.2.2.2 Puncture resistance test of flexible knob

If the soother is fitted with a flexible knob repeat the puncture resistance test on the knob in a similar manner to that described in 6.2.2.1.

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**Figure 8 – Indentor for the puncture and tear test**

6.2.3 Tear resistance test

6.2.3.1 Tear resistance test of teat

Using a complete new soother sample place the indentor, the shape and dimensions of which are given in Figure 8, with the 3 mm edge of the indentor centred over and at right angles to the major axis of the soother and (7.5 ± 0.5) mm from the front face of the shield.

Apply a load ensuring that the indentor cuts through both walls of the teat and approximately 1 mm into the cutting board.

After this treatment the soother shall be tensile tested by holding the shield in a suitable fixture and applying the force (90 ± 5) N to the teat at right angles to the major axis of the soother according to 6.2.7.1. The shield shall be held so that the uppermost hole made by the indentor is facing upwards i.e. it is subjected to the maximum tearing force.
6.2.3.2 Tear resistance test of flexible knob

If the soother is fitted with a flexible knob, repeat the tear resistance test on the knob in a similar manner to that described in 6.2.3.1.

6.2.4 Knob, plug and/or cover retention test

The back face of the shield shall be supported as in Figure 9. The support shall be close to the knob, plug and or cover, but without making contact. Certain soothers fitted with rings require slots in the soother support in order to achieve a good fit on the back of the shield (see Figure 9).

Cut the tip off the teat at 5 mm to 10 mm from the teat/shield junction. Place a 5 mm diameter rod with a flat end into the teat until it rests on the plug or the combined plug and cover. Apply a force of (90 ± 5) N at a crosshead speed of (10 ± 1) mm/min and maintain for (10 ± 0,5) s.

If the soother is fitted with a separate plug and knob or cover then all parts shall be tested. Apply the force to the underside of the knob or cover e.g., by drilling a hole in the centre of the plug to allow access for the test rod, or by such other means as the design of the soother might allow.

In cases where a 5 mm diameter rod is not satisfactory, an alternative rod having a round or flattened cross section of a suitable size shall be used.
6.2.5 Biting endurance test

6.2.5.1 Procedure for setting the test jaws

Carry out the following procedure to ensure that the top and bottom jaws are correctly aligned. Position a piece of card between the jaws, and apply a compressive force of about 50 N. Release the force and remove the card. To check the alignment of the indentations on both sides of the card, push a pin through the centre of one indentation and inspect the opposite side of the card to confirm that the pin is also in the centre of the opposite indentation.

6.2.5.2 Test procedure

Place the soother whose teat is to be tested between the stainless steel jaws as shown in Figures 10 and 11, such that the full force is applied by the biting edges, between the teat and the shield. Apply a minimum load of \((200 \pm 10)\) N to hold the soother. Apply a maximum load of \((400 \pm 10)\) N and minimum load of \((200 \pm 10)\) N as the upper jaw cycles up and down 50 times at a crosshead speed of \((10 \pm 1)\) mm/min.
Figure 10 – Positioning of the soother for the biting endurance test

After this treatment the soother shall be tested for tensile strength by holding the shield in a suitable fixture and by applying the force to the teat at right angles to the major axis of the soother, according to 6.2.7.1.

The shield shall be held so that the part of the teat pressed repeatedly by the jaw is facing upwards i.e., it is subjected to the maximum tearing force.

NOTE 1  It is essential that the biting edges do not move out of line in use. Guide bars can be provided in order to ensure that this is achieved.

NOTE 2  In some cases the soother can move during the test so the position contacted by the biting edges is not constant. It is allowable to support the shield of the soother to ensure that this does not happen.

6.2.5.3 Biting endurance procedure for soft flexible knobs

The knob shall be pressed sideways against the shield or any raised piece of the soother on that side of the shield. One jaw shall press on the knob and the other on the teat face of the shield. The tensile strength test shall be carried out as given in 6.2.5.2, with the part of the knob pressed by the jaw facing upwards, i.e., it is subjected to the maximum tearing force.
6.2.6 Rotation endurance test

This test is applicable to soothers, where any part can rotate inside the teat according to 5.6.

Clamp the shield securely and rotate the knob, plug, cover or ring at a speed of \((50 \pm 5)\ \text{rev-min}^{-1}\), 250 revolutions in a clockwise direction, then 250 revolutions in a counter clockwise direction.

After this treatment the soother shall be tested for tensile strength according to 6.2.7.1 applying the force between the shield and the teat along the major axis of the soother.
6.2.7 Integrity tests

6.2.7.1 General instructions for all tensile tests

Clamp the teat (12 ± 2) mm from the shield.

Rings shall be held by a clamp, rod or by a hook. Two rods or hooks can be used if the shape of the ring prevents it from being held securely in the required position. Each rod or hook shall have a diameter of 5 mm and have a circular cross section.

All other components shall be held by clamps or other devices.

Examples of some suitable devices are given in annex A (informative).

Clamps or other devices shall hold the components securely during the test without giving rise to damage which might affect the test result. Any results where such damage occurs shall be disregarded.

The tensile force shall be applied to one component of the soother whilst another part is firmly held. A preload of (5 ± 2) N shall be applied to align the specimen and then the force shall be increased to (90 ± 5) N at a crosshead speed of (200 ± 5) mm/min and maintained at that level for (10 ± 0,5) s.

NOTE The force used is not applicable for the reference test method given in annex B.

In some cases the design of the soother makes it impossible to apply a force exactly at right angles to its major axis, e.g., when the side of the teat contacts the edge of the shield. In such cases, the force shall be applied as near as is practical to a right angle, whilst ensuring that any residual contact between the two parts shall not significantly reduce the force actually applied to their junction.

When the force is applied at right angles to the axis, to a component which does not have a circular section about the main axis of the soother, then the test shall be carried out on two samples. The force shall be applied, once to each sample, 90° apart, and as far as possible in line with the extremes of the section.

6.2.7.2 Additional tests

Additional tests to those in 6.2.1 to 6.2.6 shall be carried out, to ensure the integrity of all components. The force specified in 6.2.7.1 shall be applied along the major axis and at right angles to the major axis.

All single components shall be tested, and also every possible combination of pairs of components, where this has not been carried out in other tests.

As the purpose of this series of tests is to reduce the risk of the soother coming apart, the forces shall be applied in the most onerous position.

The following are additional examples of the likely suitable combinations which need to be tested dependent on the design of the soother.

(a) Ring/ring

(b) Ring/shield

   Shield/shield (2-component shield e. g. rattle shield)

   Knob/cover/plug - knob/cover/plug (2-components)

(c) Knob/cover/plug - shield

This is not an exhaustive list of such additional tests. Other constructions/designs could have other pairs of components which shall be tested.
Some examples of suitable tests are shown in Figure 12.

**Key**

1. Major axis
2. Clamping device
A. Ring - ring
B. Ring - shield
C. Knob / cover / plug - shield
D. Shield – shield (2-component rattle shield)

**Note** The hatched boxes indicate the component part is fixed or clamped in place.

Figure 12 – Examples of additional tests on soother components
Annex A
(informative)

Some examples of suitable fixing devices

Key
A Front view
B Side view

Figure A.1 - Examples of suitable fixing devices for tensile tests along the major axis
Key
A Front view
B Side view

Figure A.2 - Example of a suitable fixing device for tensile tests at right angles to the major axis
Key

1 - Y axial movement
2 +Y axial movement
3 Translation tables
4 - X axial movement
5 +X axial movement
6 - Y axial movement of the fixture
7 +Y axial movement of the fixture
8 - X axial movement of the fixture
9 +X axial movement of the fixture
10 Tensile force (front view)
11 Tensile force (side view)

Figure A.3 – Example of an axial auto-centring system for assisting alignment of soother teat when tensile testing at right angles to major axis
Annex B
(informative)

Soothers - Assessment of compliance with standard - Sampling plan and compliance levels for freshly manufactured samples

B.1 General

This annex does not apply for samples purchased in stores.

If a party wishes to establish, by inspection and testing of samples of the final product, whether a batch of soothers produced to EN 1400 complies with the requirements, the sampling plans in B.2 to B.5 can be applied.

For example:

a) type-testing of product;

b) for contractual purposes by a purchaser;

c) by a national inspection authority.

This annex takes into account the inevitable variation which occurs in the manufacturing processes. However, if any test produces a result lower than the minimum requirement (90 N) given in Part 2 body of the standard, the soother shall be deemed to have failed. The tests are designed to be carried out until the sample(s) break and therefore a higher threshold value has been used than in Part 2 of the standard.

B.2 Sampling

A single or double sampling plan can be used.

Each lot should be sampled in accordance with ISO 2859-1, special inspection level S-4.

NOTE 1 It is necessary to know the batch size in order to derive from ISO 2859-1 the number of samples to be tested. The batch size varies between manufacturers and is regarded as part of the process and quality controls used by the manufacturer.

NOTE 2 If the size of the batch from which the soothers in question were derived is unknown, it should be assumed that the batch size is between 35 001 and 150 000.

B.3 Compliance level

AQL of 1,0 for 120 N.

B.4 Test methods and procedure

The soother is to be tested in accordance with clause 6 of EN 1400-2:2002.

NOTE The requirements given in EN 1400-2 for mechanical properties are intended to be applied to soothers at time of selling and even after they have been in stock for some time. Therefore an oven treatment procedure (artificial ageing) intended to simulate the effect of normal storage is included for freshly made soothers.
EN 1400-2:2002 (E)

Part 2, 6.2.1, 6.2.3, 6.2.5 and 6.2.6

The final tensile strength tests are to be carried out to failure.

Part 2, 6.2.7.2 and 6.2.4

The tests are to be carried out to failure.

B.5 Threshold value

120 N