



SLOVENSKI STANDARD

SIST EN 1400-2:2003

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

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

Artikel für Säuglinge and Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Teil 2 :
Mechanische Anforderungen und Prüfungen

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Articles de puériculture - Sucettes pour nourrissons et jeunes enfants - Partie 2 :
Exigences mécaniques et essais

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ICS 97.190

English version

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

Articles de puériculture - Sucettes pour nourrissons - Partie 2 : Exigences mécaniques et essais

Artikel für Säuglinge und Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Teil 2 : Mechanische Anforderungen und Prüfungen

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

	page
Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions.....	5
4 Description of a soother.....	7
5 Performance of the soother	10
5.1 Impact resistance.....	10
5.2 Puncture resistance.....	10
5.3 Tear resistance.....	11
5.4 Knob, plug and/or cover retention	11
5.5 Biting endurance.....	11
5.6 Rotation endurance	11
5.7 Integrity.....	11
6 Testing	12
6.1 Preparation of samples and general testing methods for oven treatment	13
6.2 Test methods.....	13
Annex A (informative) Some examples of suitable fixing devices	22
Annex B (informative) Soothers - Assessment of compliance with standard - Sampling plan and compliance levels for freshly manufactured samples	25
B.1 General.....	25
B.2 Sampling	25
B.3 Compliance level.....	25
B.4 Test methods and procedure.....	25
B.5 Threshold value	26

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*.

EN ISO 1302, *Geometrical Product Specifications (GPS) - Indication of surface texture in technical product documentation (ISO 1302:2002)*.

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

EN ISO 3696, *Water for analytical laboratory use - Specification and test methods (ISO 3696:1987)*.

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

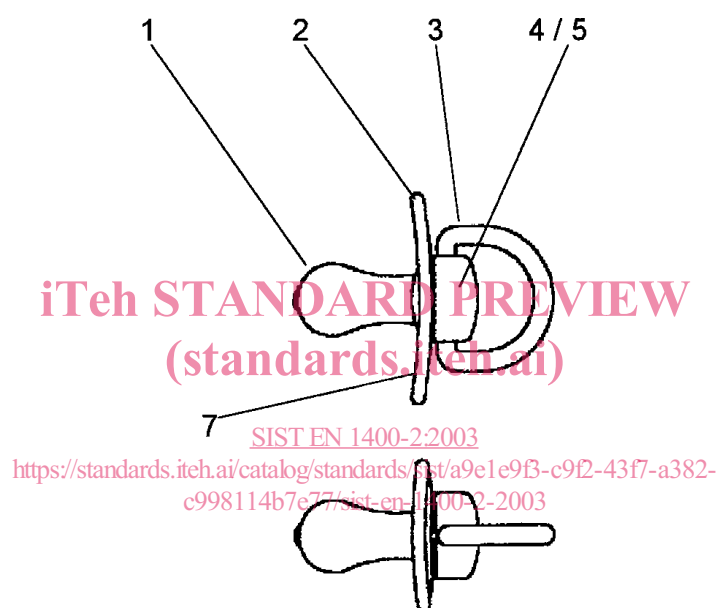
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4 Description of a soother

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

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

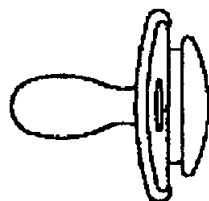
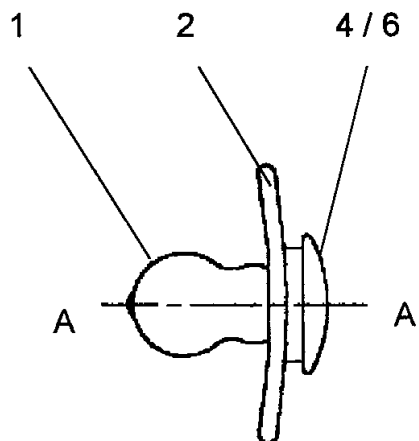
NOTE Similar components are marked with the same number in Figures 1 to 4.



Key

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

Figure 1 – Example of a soother with ring



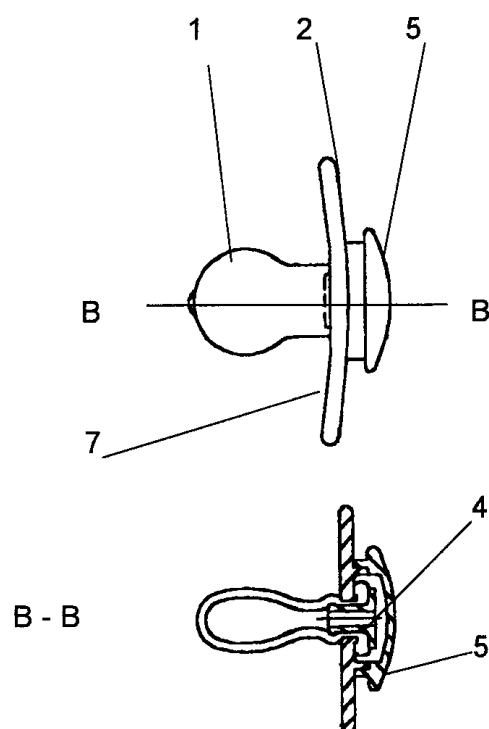
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Key

- 1 Teat
- 2 Shield
- 4 Plug
- 6 Knob

Figure 2 – Example of a soother with knob



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Key

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

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Figure 3 – Example of a soother with plug and cover