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Child care articles - Soother holder - Safety requirements and test methods

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/25

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 12586

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Supersedes EN 12586:2007+A1:2011

English Version

**Child care articles - Soother holder - Safety requirements
and test methods**

Articles de puériculture - Attache-sucette - Exigences
de sécurité et méthodes d'essai

Artikel für Säuglinge und Kleinkinder - Schnullerhalter
- Sicherheitstechnische Anforderungen und
Prüfverfahren

This European Standard was approved by CEN on 1 December 2024.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN 12586:2025 (E)

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European foreword

This document (EN 12586:2025) has been prepared by Technical Committee CEN/TC 252 “Child 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of an identical text or by endorsement, at the latest by October 2025, and conflicting national standards shall be withdrawn at the latest by April 2026.

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

This document supersedes EN 12586:2007+A1:2011.

EN 12586:2024 includes the following significant technical changes with respect to EN 12586:2007+A1:2011:

- The standard has been completely renewed and a new structure was given. A whole series of new aspects had to be considered.
- The list of materials used currently for soother holders is wider than the list in the former edition, therefore additional materials have been included (silicone elastomer, rubber, TPE, leather, resin-bonded materials).
- Introduction: Double testing should be avoided for environmental protection reasons. Therefore, substances regulated by REACH like phthalates, nickel are not included any more.
- 7.3: The list of chemical elements to be tested for migration of certain elements has been enlarged to cover 19 elements in accordance with the last amendment of Directive 2009/48/EC.
- 7.4: Colour fastness test was changed and split in first action and final action method.
- 7.7: Limits and test methods for formaldehyde release from different materials have been revised and modified and included in a separate paragraph. The test and the limit for formaldehyde release is set based on the pragmatic approach that independently of the material type the amount of formaldehyde migrating from the entire product into saliva simulant shall not exceed the health-based limit.
- 7.8: Migration limits for BPA, phenol have been revised and set based on the recent amendments of Appendix C to Annex II of Directive 2009/48/EC.
- 7.9 and 7.10: The list of preservatives was enlarged to cover wood and leather preservatives too.
- Annex B: The specific migration limits have been specified based on the migration scenario usually applied in the childcare article standards drafted by TC 252 WG5, considering the allocated daily intake, the body weight, and the likely exposure.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

EN 12586:2024 (E)

NOTE Information about interpretations of CEN TC 252 Standards can be found in the collection of interpretation requests CEN/TR 16411:2022 [31].

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

Accidents caused by soothers are few and any resulting in the death of a child are unknown. However, a small number of children die as a result of accidents where a soother is involved, but in these cases, death almost always results from strangulation by a cord being used to hang the soother around the child's neck. Such cords are usually either home-made or made for some other purpose, e.g. a coiled key ring holder.

The main aim of this document is to eliminate the risk of strangulation. This has only been made possible by severely restricting the length of the soother holder. The length should be sufficient for its purpose while not being so long that the strap can encircle the neck and strangle even the smallest child. The lack of reported incidents involving accidents or fatalities since its introduction would suggest that this document has achieved this main aim.

A functional soother holder is not to be considered as a toy. However, a soother holder may contain a part or be designed in such a way as to present a dual use. If the soother holder, in addition to its functional use, has a significant play value, it could also be considered as a toy.

Chemical hazards have been considered by the Technical Committee for all construction materials normally encountered in soother holders. Where relevant, requirements have been derived and included in this document. Restrictions for phthalates, for poly aromatic hydrocarbons (PAH) and for the release of nickel have not been included in this document as they are regulated by REACH [1] (See also part 7.1). Flame retardants are not included as they are regulated by REACH and Regulation (EU) 2019/1021 [2] and do not have any relevance to functional soother holders.

Products with claimed biocidal effect or intended biocidal action are falling under the scope of Regulation (EU) No 528/2012 concerning the marketing and use of biocidal products [3].

A normative annex has been included which contains translations of warning phrases into the main European languages.

It is recommended that manufacturers and suppliers operate to EN ISO 9001 for quality management systems [4]. It is also recommended that laboratories operate to ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories [5].

It is also important that the product or its packaging bears a traceability marking (e.g. batch coding) to enable traceability of the product through the supply chain.

EN 12586:2024 (E)**1 Scope**

This document specifies safety requirements relating to materials, construction, performance, packaging and labelling of soother holders.

NOTE 1 See B.1.

It includes test methods for the mechanical and chemical requirements specified.

This document covers products for children from birth to 36 months of age, alike the soothers to which these items are connected to.

This document is intended to provide safety requirements for soother holders. All products that allow the attachment of a soother intended for babies and young children to any other object are included in the scope. The soother holder has a holding device at one end for the soother, a garment fastener that attaches to any other product, e.g. the child's garment and a connecting device linking these parts. The safety requirements of products that a soother holder attaches to are not considered in this standard.

Where a soother holder is considered to have significant play value, the soother holder is expected to meet the safety requirements for toys as stated in the Toy Directive 2009/48/EC [6] in addition to those in this document.

NOTE 2 See B.2.

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.

EN 71-1:2014+A1:2018, *Safety of toys - Part 1: Mechanical and physical properties*

EN 71-3:2019+A1:2021, *Safety of toys - Part 3: Migration of certain elements*

EN 71-10:2005, *Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction*

EN 71-11:2005, *Safety of toys - Part 11: Organic chemical compounds - Methods of analysis*

EN 71-12:2016, *Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances*

ISO 4593:1993, *Plastics — Film and sheeting — Determination of thickness by mechanical scanning*

EN 17394-2:2020, *Textiles and textile products - Part 2: Safety of children's clothing - Security of attachment of buttons - Test method*

CEN/TS 17394-3:2021, *Textiles and textile products - Part 3: Safety of children's clothing - Security of attachment of metal mechanically applied press fasteners - Test method*

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