

LASTELE KASUTAMISEKS JA LASTE HOOLDAMISEKS
MÕELDUD TOOTED. RÕNGASLUTID IMIKUTELE JA
VÄIKELASTELE. OHUTUSNÕUDED JA KATSEMEETODID

Child use and care articles - Soothers for babies and
young children - Safety requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 1400:2013+A2:2018 sisaldab Euroopa standardi EN 1400:2013+A2:2018 ingliskeelset teksti.	This Estonian standard EVS-EN 1400:2013+A2:2018 consists of the English text of the European standard EN 1400:2013+A2:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 05.09.2018.	Date of Availability of the European standard is 05.09.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 97.190

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

Child use and care articles - Soothers for babies and young children - Safety requirements and test methods

Articles de puériculture - Sucettes pour nourrissons et jeunes enfants - Exigences de sécurité et méthodes d'essai

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

This European Standard was approved by CEN on 25 February 2014 and includes Amendment 1, approved by CEN on 2014-02-25 and Amendment 2, approved by CEN on 2018-04-23.

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

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

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

Contents	Page
European foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Description of a soother	7
5 Test equipment	11
6 General	18
7 Printing and decals	21
8 Construction properties and tests	21
9 Mechanical properties	35
10 Chemical requirements and test methods	43
11 Teat protectors	51
12 Consumer packaging	53
13 Product information	53
14 Test report	55
Annex A (normative) Warnings	57
Annex B (informative) Rationale	61
Annex C (informative) Information for products resembling a soother	73
Annex D (informative) Some examples of suitable fixing devices	75
Annex E (informative) Soothers — Assessment of compliance with standard — Sampling plan and compliance levels for freshly manufactured samples	78
Annex F (informative) A suitable HPLC apparatus and method for determination of 2-Mercaptobenzothiazole (MBT) and antioxidants BHT, 2246, Cyanox 425, Wingstay L and Irganox 1520	79
Annex G (informative) Graphical representation for determining puncture resistance of a teat	83
Annex H (informative) A-deviations	84
Bibliography	85

European foreword

This document (EN 1400:2013+A2:2018) 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 March 2019, and conflicting national standards shall be withdrawn at the latest by March 2019.

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 includes Amendment 1, approved by CEN on 2014-02-25 and Amendment 2, approved by CEN on 2018-04-23.

This document supersedes A2 EN 1400:2013+A1:2014 A2.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1 and A2 A2.

This document has been prepared under a mandate (M/264) given to CEN by the European Commission and the European Free Trade Association.

This standard is linked to the General Product Safety Directive (GPSD) but no Annex ZA is needed because GPSD is not a New Approach Directive and does not include Essential Requirements to which such an annex should refer.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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 harmonises minimum safety requirements and test methods for soothers. Most of the provisions have been taken from other existing national and European Standards.

It is recommended that manufacturers and suppliers operate to EN ISO 9001, the standard for quality management systems [1]. It is also recommended that laboratories operate to ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories [4].

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 E (informative). This procedure can be used as a voluntary type approval procedure.

Latex protein allergy risk has not been included in this standard. Nevertheless, provision for packaging information for soothers containing natural rubber has been made in this standard. There is no published information that sensitisation is caused by soother teats. In addition, there is an extremely low incidence of latex protein allergy among young children and babies. However, the issue of subsequent allergic reaction from rubber teats will be reconsidered when further information becomes available.

Phthalates have not been included in this standard because the use of phthalates in childcare articles is restricted by Annex XVII of REACH Regulation [5].

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

A2 Since the publication of EN 1400:2013+A1:2014 it has come to the attention of the Technical Committee that some of the TDI's used to calculate the limits of a certain number of element migration from soothers are out of date. During the drafting of this amendment the Technical committee reviewed all the previous sources of TDI's to ascertain the current state of knowledge.

The migration limits for Arsenic, Barium, and Nickel have been changed to reflect the latest information. In addition migration limits for Chromium VI and Organic Tin have been added.

The Technical Committee has also included a requirement for Bisphenol A (BPA) in soothers based on the most recent TDI from the 2015 EFSA Opinion and an A-Deviation from France. **A2**

1 Scope

This European Standard specifies safety requirements relating to the materials, construction, performance, packaging and product information for soothers.

This European Standard is applicable to products that resemble or function as a soother. Some soothers may be marketed with other functions. This standard is applicable to these products (some examples are given in Annex C).

This European Standard does not apply to products designed for specialist clinical medical applications, e.g. those relating to Pierre-Robin Syndrome or premature babies (see Annex C).

The standard is not applicable to feeding teats. Safety requirements and test methods for feeding teats are included in all parts of EN 14350 [2], [3].

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

DIN 53160-1, *Determination of the colourfastness of articles for common use — Part 1: Test with artificial saliva*

EN 71-1, *Safety of toys — Part 1: Mechanical and physical properties*

EN 71-3, *Safety of toys — Part 3: Migration of certain elements*

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

EN 12868, *Child use and care articles — Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers*

EN 20105-A03, *Textiles — Tests for colour fastness — Part A03: Grey scale for assessing staining (ISO 105-A03)*

EN ISO 1302, *Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation (ISO 1302)*

EN ISO 3696, *Water for analytical laboratory use — Specification and test methods (ISO 3696)*

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

3 Terms and definitions

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

3.1

soother

article which includes a teat and which is intended to satisfy the non-nutritive sucking need of children

Note 1 to entry: Soothers are also known as pacifiers or babies' dummies.

3.2

teat

part of the soother designed to be placed in the mouth