



# SLOVENSKI STANDARD

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

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

Artikel für Säuglinge und Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Teil 3 : Chemische Anforderungen und Prüfungen

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Articles de puériculture - Sucettes pour nourrissons et jeunes enfants - Partie 3: Exigences chimiques et essais

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English version

## Child use and care articles - Soothers for babies and young children - Part 3 : Chemical requirements and tests

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

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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 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

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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of an identical text or by endorsement, at the latest by March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.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" 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 one annex:

- annex A (informative) A suitable HPLC apparatus, method and precision data for determination of 2-Mercaptobenzothiazole (MBT) and/or antioxidants

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

Elastomeric and rubber teats are regulated by the Commission Directive 93/11/EEC concerning the release of *N*-Nitrosamine and *N*-Nitrosatable substances from elastomer or rubber teats and soothers. The current Directive provides in its annexes an outline method of analysis which, has been published as EN 12868.

A limit for the release of 2-mercaptobenzothiazole (MBT) has been specified in the standard. This limit significantly reduces the level of this substance potentially released from soothers. The Scientific Committee for Food has concluded that the limit does not constitute a health hazard. The limit for the release of MBT will be reconsidered in light of future studies and recommendations.

It is noted that all plastic components are regulated by the Commission Directive 90/128/EEC.

Commission Decision 198/815/EC with its subsequent extensions has adopted temporary measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age. The prohibition relates to such products made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP). At the time of preparing this standard a final decision was awaited. This standard will be reviewed in the light of that decision.

Formaldehyde, caprolactam and colourants have each been considered by the Technical Committee. They have not been included in the standard at this stage because of the lack of either adequate information for making a satisfactory potential risk assessment, or validated test methods for the determination of their migration levels from relevant products. They will be reconsidered when further information becomes available.

For similar reasons, latex protein allergy risk has also not been included in this standard. There is an extremely low incidence of latex protein allergy amongst babies and young children. Nevertheless, provision for packaging information for soothers containing natural rubber has been made in Part 1 of this standard. The issue of potential sensitisation and allergic reaction from rubber products will be re-considered when further information becomes available.

## 1 Scope

This part of this European Standard specifies limits and test methods for the release of certain chemicals from materials used for the manufacture of soothers.

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.<sup>1</sup>

## 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 71-3, *Safety of toys - Part 3: Migration of certain elements*.

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

## 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

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

<sup>1</sup> A standard for safety requirements and test methods for drinking equipment is in preparation.

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 Chemical requirements**

**4.1 General**

Materials used for manufacturing soothers shall be subjected to the sample preparation as specified in 5.1 and the tests listed in Table 1.

NOTE 1 Additional information for the finished product can be obtained from Directive 90/128/EEC [1] and the Commission of the European Communities [2]  
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NOTE 2 It is recommended that manufacturers and suppliers operate to EN ISO 9001 [3] for quality management.

**4.2 Chemical properties**

The vulcanising agents (e.g. MBT) and antioxidants mentioned below do not represent a definitive list. Chemicals other than those mentioned in this standard can be used where toxicological evidence, either on the original chemical or any reaction product, is available to demonstrate that no unacceptable risk is posed when they are used in soothers and an appropriate analytical test procedure for determining migration levels exists.

**4.3 Requirements by material**

Materials used in the manufacture of components of soothers shall be subjected to the tests marked with an x in Table 1.



Table 1 — Tests to be carried out on materials

Material	Tests				
	Migration of certain elements  (see 5.2)	N-Nitrosamines and N-Nitrosatable substances release  (see 5.3)	MBT release  (see 5.4)	Anti-oxidants release  (see 5.4)	Volatile compounds content  (see 5.5)
Vulcanized rubber	x	x	x	x	
Silicone rubber	x	x			x
Thermoplastic elastomers (TPEs)	x	x			
Thermoplastics	x				

#### 4.4 Migration of certain elements

When tested in accordance with 5.2 the migration of elements from all material(s) used in the manufacture of soothers shall not exceed the limits given in Table 2.

When soothers contain components manufactured from different material(s), or in different colours, all components shall be tested individually. Decorations shall be considered to be part(s) of the material(s) on which they are printed.

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Table 2 — Limits of element migration from soothers

Element	Limit (mg/kg)
Antimony, Sb	15
Arsenic, As	10
Barium, Ba	100
Cadmium, Cd	20
Lead, Pb	25
Chromium, Cr	10
Mercury, Hg	10
Selenium, Se	100

NOTE The analytical method specified in EN 71-3 has been applied in this standard to soothers. The limits set account for the prolonged sucking of a teat in the mouth.

#### 4.5 N-Nitrosamines and N-Nitrosatable substances release

When tested in accordance with 5.3, the total N-Nitrosamines and N-Nitrosatables release of any elastomer or rubber component shall not exceed the limits given in Table 3.