



National Standards Authority of Ireland

IRISH STANDARD

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ICS 97.190

**CHILD USE AND CARE ARTICLES -  
SOOTHERS FOR BABIES AND YOUNG  
CHILDREN - PART 1: GENERAL SAFETY  
REQUIREMENTS AND PRODUCT  
INFORMATION**

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English version

**Child use and care articles - Soothers for babies and young children - Part 1: General safety requirements and product information**

Articles de puériculture - Sucettes pour nourrissons et jeunes enfants - Partie 1 : Exigences générales et informations relatives au produit

Artikel für Säuglinge und Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Teil 1 : Allgemeine Sicherheitstechnische Anforderungen und Produktinformationen

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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# EN 1400-1:2002 (E)

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## **Foreword**

This document EN 1400-1:2002 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of an identical text or by endorsement, at the latest by March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.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 EN 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 one annex:

- annex A (informative) *Information for medical devices*

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.

## EN 1400-1:2002 (E)

### 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 Part 2, annex B (informative). This procedure can be used as a voluntary type approval procedure.

It is noted that all plastic components are regulated by the Commission Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs.

NOTE It is also noted that the release of *N*-nitrosamines and *N*-nitrosatable substances from elastomer or rubber teats and soothers is controlled by the provisions of Commission Directive 93/11/EEC.

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