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

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

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Deze Europese norm EN 1400-3 : 2002 heeft de status van een Belgische norm.

Deze Europese norm bestaat in drie officiële versies (Duits, Engels, Frans).



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English version

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

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

Artikel für Säuglinge und Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Teil 3 : Chemische 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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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of an identical text or by endorsement, at the latest by March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.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.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 71-3, *Safety of toys - Part 3: Migration of certain elements*.

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

¹ A standard for safety requirements and test methods for drinking equipment is in preparation.