



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 1400-3:2002

ICS 97.190

**CHILD USE AND CARE ARTICLES -
SOOTHERS FOR BABIES AND YOUNG
CHILDREN - PART 3: CHEMICAL
REQUIREMENTS AND TESTS**

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel (01) 807 3800
Tel (01) 807 3838

*This Irish Standard was
published under the
authority of the National
Standards Authority of
Ireland
and comes into effect on
November 6, 2002*

**NO COPYING WITHOUT NSAI
PERMISSION EXCEPT AS
PERMITTED BY COPYRIGHT
LAW**

© NSAI 2002

Price Code F

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1400-3

September 2002

ICS 97.190

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.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN 1400-3:2002 (E)

Contents

	page
Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions.....	5
4 Chemical requirements	6
4.1 General.....	6
4.2 Chemical properties	6
4.3 Requirements by material	6
4.4 Migration of certain elements	7
4.5 <i>N</i> -Nitrosamines and <i>N</i> -Nitrosatable substances release	7
4.6 Mercaptobenzothiazole (MBT) release	8
4.7 Antioxidants release	8
4.8 Volatile compounds content.....	8
5 Test methods.....	8
5.1 Sample preparation	8
5.2 Determination of the migration of certain elements.....	9
5.3 Determination of <i>N</i> -Nitrosamines and <i>N</i> -Nitrosatable substances release	10
5.4 Determination of 2-Mercaptobenzothiazole (MBT) and antioxidants release.....	10
5.5 Determination of volatile compounds content	12
Annex A (informative) A suitable HPLC apparatus, method and precision data for determination of 2-Mercaptobenzothiazole (MBT) and/or antioxidants.....	13
Bibliography	15

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.

EN 1400-3:2002 (E)

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.

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-