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Child use and care articles - Drinking equipment -
Part 2: Chemical requirements and tests

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 14350-2:2004 sisaldab Euroopa standardi EN 14350-2:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 23.11.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 14350-2:2004 consists of the English text of the European standard EN 14350-2:2004.</p> <p>This document is endorsed on 23.11.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This European Standard specifies limits for the release of certain chemicals from materials to be used for the manufacture of : - reusable feeding teats and drinking accessories ; - reusable feeding bottles and drinking cups ; - single-use feeding bottles, feeding teats, drinking accessories and single-use feeding bags. It includes test methods for the chemical safety requirements specified</p>	<p>Scope:</p> <p>This European Standard specifies limits for the release of certain chemicals from materials to be used for the manufacture of : - reusable feeding teats and drinking accessories ; - reusable feeding bottles and drinking cups ; - single-use feeding bottles, feeding teats, drinking accessories and single-use feeding bags. It includes test methods for the chemical safety requirements specified</p>
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ICS 97.190

English version

**Child use and care articles - Drinking equipment - Part 2:
Chemical requirements and tests**

Articles de puériculture - Articles pour l'alimentation liquide
- Partie 2: Exigences chimiques et essais

Artikel für Säuglinge und Kleinkinder - Artikel für flüssige
Kindernahrung - Teil 2: Chemische Anforderungen und
Prüfungen

This European Standard was approved by CEN on 30 April 2004.

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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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN 14350-2:2004) 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 February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

This European Standard EN 14350 "Child use and care articles – Drinking equipment" consists of the following parts:

- *Part 1: General and mechanical requirements and tests*
- *Part 2: Chemical requirements and tests*

Introduction

This document establishes minimum safety requirements and gives appropriate test methods for children's drinking equipment.

The complete document harmonises, for the first time, minimum safety requirements and test methods for children's drinking equipment. Some 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 document. Any claim relates to all published parts.

The use of this document may involve hazardous materials, operations and/or equipment. This document does not purport to address all the safety problems associated with its use. It is the responsibility of the user of this document to establish appropriate health and safety practices and determine the applicability of regulatory limitations prior to its use.

It is recommended that manufacturers and suppliers operate to EN ISO 9001 [7] standard for quality management systems.

Elastomeric and rubber teats are regulated by the Commission Directive 93/11/EEC [1] 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 that 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 children's drinking equipment. The Scientific Committee for Food has concluded that the limit does not constitute a health hazard. The limit for release of MBT will be reconsidered in light of future studies and recommendations.

A limit for the release of 2,2-bis(4-hydroxyphenyl)propane [Bisphenol A] (BPA) has been specified in the standard. The Scientific Committee for Food has concluded that the (temporary) limit (t-TDI) does not constitute a health hazard. The limit for release of BPA will be reconsidered in light of future studies and recommendations.

It is noted that all plastics components of drinking equipment are regulated by the Commission Directive 2002/72/EC [2] relating to plastics materials and articles intended to come into contact with foodstuff.

Commission Decision 99/815/EC [3], 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 document a final decision was awaited. This document will be reviewed in the light of that decision.

The Technical Committee has considered the issues relating to phthalate plasticiser migration from child use and care articles not intended to be placed in the mouth. Recognising the inadequacies of the only currently validated (static) test method for plasticiser migration from PVC [8], the Committee has developed an improved test to provide migration data under more realistic (dynamic) conditions of exposure. However, the Technical Committee will consider the official European method prior to its application to drinking equipment; such child use and care articles may require additional or alternative measures due to the mode of usage of drinking equipment and their potentially longer periods of exposure to babies and young children. After this consideration, an amendment to this document may be made.

Formaldehyde, caprolactam and colorants have each been considered by the Technical Committee. They have not been included in the document 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 document. There is an extremely low incidence of latex protein allergy amongst babies and young children. Nevertheless, provision for information for drinking equipment containing natural rubber latex has been made in Part 1 of this document. The issue of potential sensitisation and allergic reaction from rubber products will be reconsidered when further information becomes available.

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1 Scope

This part of this document specifies limits for the release of certain chemicals from materials to be used for the manufacture of the following drinking equipment:

- Re-usable feeding teats and drinking accessories;
- Re-usable feeding bottles and drinking cups;
- Single-use feeding bottles, feeding teats, feeding bags and drinking accessories, which do not contain fluid when purchased.

It includes test methods for the chemical safety requirements specified.

It does not apply to drinking equipment designed for medical applications or for use under medical supervision.

This document is not applicable to soothers. Safety requirements and test methods for soothers are specified in EN 1400-1, EN 1400-2 and EN 1400-3.

2 Normative references

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

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 document, the following terms and definitions apply.

3.1

feeding teat

substitute mother's nipple that when attached to a container permits a child to obtain fluid by suckling

3.2

drinking accessory

any device other than a feeding teat which permits a child to obtain fluid from a container

EXAMPLE feeding spout.

3.2.1

straw

hollow tube drinking accessory through which fluid is sucked

3.3

container

either a feeding bottle, drinking cup or feeding bag