



SLOVENSKI STANDARD

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

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

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

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

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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.

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 Central Secretariat 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 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of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.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*

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EN 14350-2:2004 (E)**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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EN 14350-2:2004 (E)**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

3.3.1**feeding bottle**

container which is capable of holding a fluid and incorporates a graduated scale suitable for visual measurement and is intended for feeding a child through a feeding teat or drinking accessory

3.3.2**drinking cup**

container other than a feeding bottle or feeding bag capable of holding a fluid intended for feeding a child

3.3.3**feeding bag**

bag capable of holding fluid and supported for use by a holder

NOTE Feeding bags are also known as feeding liners.

3.4**locking ring**

component used to secure a feeding teat or drinking accessory to a container

3.5**sealing disc**

component used to create a seal between the container and the locking ring

3.6**protective cover**

component to cover a feeding teat or drinking accessory

3.7**matched components**

any of the above defined components which are used together whilst feeding a child

3.8**numbered graduations**

numbered markings which indicate the volume of fluid within the container

3.9**single-use feeding teat, drinking accessory or container**

any item of drinking equipment sold for single use

3.10**re-usable**

component intended to be used again after first use

3.11**protrusions**

drinking accessory, feeding teat or spoon, excluding straws

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EN 14350-2:2004 (E)

4 Requirements

4.1 General

Materials used for the manufacture of drinking equipment shall be subjected to the tests listed in Table 1 and shall conform to 4.4 to 4.9.

NOTE 1 Additional information for the finished product can be obtained from Directives 82/711/EEC [4] and amendments 93/8/EEC and 97/48/EC, 85/572/EEC [5], 89/109/EEC [6], and 2002/72/EC [2].

NOTE 2 It is recommended that manufacturers and suppliers operate to EN ISO 9001 for quality management systems.

4.2 Chemical properties

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

4.3 Requirements by material

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

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Table 1 — Tests to be carried out on materials

Material	SIST EN 14350-2:2005					
	Migration of certain elements (see 5.2)	N-Nitrosamines and N-Nitrosatables release (see 5.3)	MBT release (see 5.4)	Anti-oxidants release (see 5.4)	BPA release (see 5.5)	Volatile compounds content (see 5.6)
Vulcanised rubber	x	x	x	x		
Silicone rubber	x	x				x
Thermoplastic elastomers (TPEs)	x	x				
Glass	x					
Thermoplastics	x				x ^a	

^a Only thermoplastics containing polycarbonate or polysulfone shall be tested for Bisphenol A release

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 drinking equipment shall not exceed the limits given in Table 2.

When drinking equipment 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.

Table 2 — Limits of element migration from drinking equipment

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 document to drinking equipment. The limits have been set based on the limit of detection for each element using commonly available analytical techniques.

4.5 *N*-Nitrosamines and *N*-Nitrosatables 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.

Table 3 — *N*-Nitrosamines and *N*-Nitrosatables release and tolerances

Substance	Limit mg/kg	Tolerance mg/kg
<i>N</i> -Nitrosamines	0,01	0,01
<i>N</i> -Nitrosatables	0,1	0,1

4.6 2-mercaptobenzothiazole (MBT) release

When elastomeric components of drinking equipment are tested according to 5.4, the migration of the following chemical shall not exceed 8 mg/kg:

2-mercaptobenzothiazole or 2(3H)-benzothiazolethione

CAS No. 149-30-4

IUPAC 1,3-benzothiazole-2-thiol

4.7 Antioxidants release

When elastomeric components of drinking equipment are tested according to 5.4, the migration of the following chemical shall not exceed 30 µg/100 ml or 60 µg/dm²:

2,6-bis(1,1-dimethylethyl)-4-methyl-phenol (BHT)

CAS No. 128-37-0

IUPAC 2,6-di-tert-butyl-*p*-cresol