Výrobky na starostlivosť o deti Vybavenie na pitie Bezpečnostné požiadavky a skúšobné metódy 94 3019

Child care articles - Drinking equipment - Safety requirements and test methods

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

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Artikel für Säuglinge und Kleinkinder - Artikel für flüssige Kindernahrung - Sicherheitstechnische Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 14 March 2020 and includes Amendment approved by CEN on 3 May 2023.

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

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European foreword

This document (EN 14350:2020+A1:2023) has been prepared by Technical Committee CEN/TC 252 "Child 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of an identical text or by endorsement, at the latest by February 2024, and conflicting national standards shall be withdrawn at the latest by August 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document includes Amendment 1 approved by CEN on 3 May 2023.

This document supersedes (A1) EN 14350:2020 (A1).

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A].

The main changes compared to the previous edition are listed below:

- The standard has been completely renewed and a new structure was given. The former two parts were joined together into one standard. A whole series of new aspects had to be considered, following changes in the market and the regulatory background.
- Introduction: Completely reworded and references to European regulations were renewed.
- Clause 3: Completely restructured and partly described in more detail. Definitions for completely new parts were added.
- Clause 4: Several completely new parts were added.
- Clause 5: This clause is completely new.
- Clause 6: This clause is completely new.
- Clause 7: The whole clause has been divided into several sub-paragraphs for individual components of drinking equipment and the associated tests to improve the clarity of the sequence. Several paragraphs for new items and their tests were added.
- Clause 8: This clause was completely restructured and subdivided. The requirements and test conditions have been set with the consideration of the likely chemical exposure: food contact, mouthing or ingestion. Chemical requirements and test methods were set for materials (like rubber, silicon, TPE, metal, glass) and exposures (mouthing and swallowing) which are recently not covered by harmonised legislations. Requirements for substances (e.g. Phthalates and BPA) covered by harmonised regulation (like REACH, (EU) 10/2011 or its amendments) have not been included.
- Clause 10: Revised and partly reworded.
- Clause 11: This clause on Test report is completely new.
- Annex A: This normative annex with translations of warnings into 24 languages is completely new.

- Annex B: This informative annex with rationales is completely new.
- Annex C: This informative annex on Method for the determination of 2-mercaptobenzothiazole (MBT) and antioxidants specified in Table 7 was revised and enlarged.
- Annex E: This informative annex on good practice for visibility and legibility is completely new.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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

Introduction

This document harmonises 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.

A significant choking hazard can arise if the component parts of drinking equipment become separated during use. This hazard is addressed in this document by the inclusion of a security test. However, as the fixing of such products to the container is user-dependent, the risk of an accident cannot be completely eliminated. This document sets out labelling requirements stating that parents or carers should not leave children unattended whilst being fed with a product containing a feeding teat or using a container made of glass and that children should not be allowed to use feeding teats as a soother.

The Technical Committee considered the possibility of standardizing both sizes of feeding teats and ranges of flow rates. However, it was decided that the many combinations of container systems precluded being standardized. It is recommended that all container and drinking accessory combinations are matched components. Providing meaningful flow rate information is difficult because of several factors including hole diameter, teat thickness, hole shape/type of feed, and also how individual infants suck the teat. Accordingly, it was decided not to include a test for flow rate but to recommend that manufacturers provide information on flow rate and hole size that is appropriate to their particular product.

This document sets chemical requirements and test methods for materials (like rubber, silicon, TPE etc) and exposures (mouthing and swallowing) not covered by harmonised legislations. Where this document sets migration limits for substances also covered by legislation, the requirements of this document with stated test conditions must be regarded as additional.

Materials and chemical risks included in the standard (Table 3) do not present a definitive list but the considered opinion of the Technical Committee based on current knowledge of likely risks.

All food contact materials and articles are regulated by Regulation (EC) No 1935/2004 [1], Regulation (EC) No 2023/2006 [39] and relevant implementation measures, at European or national level.

All plastics components of drinking equipment intended to come into contact with food are specifically regulated by the Regulation (EU) 10/2011 [2] on plastic materials and articles intended to come into contact with food and its amendments.

Therefore, for example the Bisphenol A - requirement has not been included in this document. [40]

Phthalates in childcare articles are restricted by Annex XVII of the REACH Regulation [3] and have not been included in this document.

Latex protein allergy risk has not been included in this document. There is no published information that sensitization is caused by feeding teats and there is an extremely low incidence of latex protein allergy among young children and babies. Nevertheless, provision for packaging information for feeding teats made from natural rubber latex has been included in this document.

It is recommended that manufacturers and suppliers operate to EN ISO 9001 standard for quality management systems [4]. It is also recommended that laboratories operate to EN ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories [5].

1 Scope

This document specifies safety requirements relating to the materials, construction, performance, packaging and product information for drinking equipment intended for children of 0 to 48 months (see B.2) of age:

- Re-usable containers and re-usable drinking accessories;
- Single-use containers and drinking accessories sold with these containers;
- Single-use feeding teats;
- Ready to use feeding teats.

This document does not include requirements for the cleanliness of ready to use and single use products.

This document does not apply to products designed for specialist clinical medical applications, e.g. those relating to cleft lip palates.

This document does not apply to drinking equipment made from ceramics.

This document does not apply to bags intended for storage only.

This document does not apply to drinking equipment which is supplied with fluids or food when purchased and to feeding accessories fixed to it.

This document is not applicable to soothers. Safety requirements and test methods for soothers are specified in EN 1400 [6].

This document is not applicable for cutlery and other feeding utensils. Safety requirements and test methods for Cutlery and other feeding equipment are specified in EN 14372 [7].

For drinking equipment excluded from the scope, consider the applicable requirements of this document whenever possible.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

- (A) EN 71-3:2019+A1:2021 (A), Safety of toys Part 3: Migration of certain elements
- (A) EN 71-11:2005, Safety of toys Part 11: Organic chemical compounds Methods of analysis
- EN 12868:2017 (A), Child use and care articles Method for determining the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers
- A) EN 60454-2:2007 (A), Pressure-sensitive adhesive tapes for electrical purposes Part 2: Methods of test (IEC 60454-2:2007)
- EN ISO 3696:1995, Water for analytical laboratory use Specification and test methods (ISO 3696:1987) (A)

ISO 188:2011, Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests

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