

MÄNGUASJADE OHUTUS. OSA 19: BISFENOL A
MIGRATSIOON MÄNGUASJADE MATERJALIDEST

Safety of toys - Part 19: Migration of bisphenol A from
toy materials

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN 71-19:2024 sisaldab Euroopa standardi EN 71-19:2024 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.12.2024.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN 71-19:2024 consists of the English text of the European standard EN 71-19:2024.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 18.12.2024.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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EUROPEAN STANDARD

EN 71-19

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2024

ICS 97.190

English Version

Safety of toys - Part 19: Migration of bisphenol A from toy materials

Sécurité des jouets - Partie 19 : Migration du bisphénol A depuis les matériaux-jouets

Sicherheit von Spielzeug - Teil 19: Migration von Bisphenol A aus Spielzeugmaterial

This European Standard was approved by CEN on 1 December 2024.

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European foreword

This document (EN 71-19:2024) has been prepared by Technical Committee CEN/TC 52 "Safety of toys", the secretariat of which is held by DS.

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of an identical text or by endorsement, at the latest by June 2025, and conflicting national standards shall be withdrawn at the latest by June 2025.

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 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.

Additional information on the background and rationale for various requirements are given in Annex A.

This document constitutes the 19th part of the EN 71 series of standards on safety of toys.

EN 71, *Safety of toys*, consists of the following parts:

- *Part 1: Mechanical and physical properties;*
- *Part 2: Flammability;*
- *Part 3: Migration of certain elements;*
- *Part 4: Experimental sets for chemistry and related activities;*
- *Part 5: Chemical toys (sets) other than experimental sets;*
- *Part 7: Finger paints — Requirements and test methods;*
- *Part 8: Activity toys for domestic use;*
- *Part 10: Organic chemical compounds — Sample preparation and extraction;*
- *Part 11: Organic chemical compounds — Methods of analysis;*
- *Part 12: N-Nitrosamines and N-nitrosatable substances;*
- *Part 13: Olfactory board games, cosmetic kits and gustative games;*
- *Part 14: Trampolines for domestic use;*
- *Part 15: Formamide in foam toy materials (content) (under development);*
- *Part 16: Certain chlorinated phosphorus flame retardants (TCEP, TCPP, TDCP) in toy materials (under development);*

- *Part 17: Certain isothiazolinones (MIT, CIT, BIT) in aqueous toy materials* (under development);
- *Part 18: Phenol in aqueous (content) and polymeric (migration) toy materials*;
- *Part 19: Migration of bisphenol A from toy materials* (this document);
- *Part 20: Microbiological safety of toys containing accessible aqueous media* (under development).

It is up to the user of the standard to determine whether or not a toy is included in the scope of several of the above parts of the EN 71 series, and to apply each applicable standard accordingly. Normative references from one part of the EN 71 series to another, are therefore normally not provided in the individual parts.

NOTE 1 In addition to the above parts of EN 71, the following deliverables have been published:

- CEN/TR 15071, *Safety of toys — National translations of warnings and instructions for use in the EN 71 series*;
- the CEN/TR 15371 series, *Safety of toys — Interpretations*;
- CEN/TR 16918, *Safety of toys — Children's mouthing behaviour in contact with toys*;
- CEN/TR 17695, *Safety of toys — Mechanical and physical properties — Guidance on categorisation of projectile toys within EN 71-1*;
- CEN/TS 17973, *Safety of toys — Categorization of slime type materials*; and
- CEN ISO/TR 8124-8, *Safety of toys — Part 8: Age determination — First age grade for the appropriate play of toys (ISO/TR 8124-8)*.

NOTE 2 Words in *italics* (apart from document titles) are defined in Clause 3 (Terms and definitions).

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.

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Introduction

According to article 46 of Directive 2009/48/EC on the safety of toys [1] the “Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth”.

In May 2017, the European Commission amended Appendix C to Annex II to this Directive accordingly and adopted a specific limit value for bisphenol A in toys (see Commission Directive (EU) 2017/898 [2]).

This document provides a test method to check compliance with this limit value.

WARNING — The application of the test method specified in this document can involve hazardous materials, operations and equipment. The document does not purport to address all of the safety or environmental problems associated with its use.

1 Scope

This document specifies requirements and a test method for migration of bisphenol A from toy materials. This document is applicable to toys intended for use by children under 36 months or other toys intended to be placed in the mouth.

NOTE The European Commission Guidance Document No 11 on the Application of Directive 2009/48/EC on the Safety of Toys [3] provides guidelines to help on the classification of toys intended for children under 36 months of age or of 36 months and over.

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.

EN ISO 3696:1995, *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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 sample

part of the toy material subject to testing

Note 1 to entry: A *sample* can consist of more than one material if the materials cannot be separated (e.g. coatings on a base material).

4 Requirements

Migration of bisphenol A from toy materials shall not exceed 0,04 mg/l when tested according to the method specified in this document.

NOTE This limit corresponds to the limit value specified in Directive 2009/48/EC [1] which was introduced by Commission Directive (EU) 2017/898 [2].

5 Principle

The migration of bisphenol A from toy material is tested by using water as simulant. Migration conditions are shaking the *sample* at 37 °C for 3 h. The migration solution is analysed using a liquid chromatography system coupled with a tandem mass spectrometer (LC-MS/MS) in multiple reaction monitoring (MRM) mode.

NOTE More information on selection of simulant and migration conditions can be found in Clause A.1.