SLOVENSKI STANDARD
oSIST prEN 71-20:2025

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[Not translated]

Safety of toys - Part 20: Microbiological safety of toys containing accessible aqueous media

Sicherheit von Spielzeug - Teil 20: Mikrobiologische Sicherheit von Spielzeug, das zugängliche wässrige Medien enthält

Sécurité des jouets - Partie 20 : Sécurité microbiologique des jouets contenant des milieux aqueux accessibles

Ta slovenski standard je istoveten z: **prEN 71-20**

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Safety of toys - Part 20: Microbiological safety of toys containing accessible aqueous media

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 52.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document prEN 71-20:2025 has been prepared by Technical Committee CEN/TC 52 “Safety of toys”, the secretariat of which is held by DS.

This document is currently submitted to the CEN Enquiry.

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.

This document constitutes the twentieth 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*;

— *Part 20: Microbiological safety of toys containing accessible aqueous media* (this document).

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 In addition to the above parts of EN 71, the following guidance documents 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 categorization 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)*.

Introduction

This document sets requirements to minimize the hazards of microbial contamination and growth in toys containing accessible aqueous media.

This document is largely based upon the requirements in ISO 8124-12 [12] and ASTM F963 [2], with some modifications to narrow the scope and facilitate use of the document. This document also takes into account the Notified Bodies Toys protocol, EC-type approval protocol No. 2. Microbiological safety of toys containing aqueous media REV 4 - NB-TOYS/2021-053 (January 2022) [4].

Conformity with the requirements of this document will minimize potential hazards associated with toys due to lack of microbiological cleanliness or inadequate preservation. Either of which can result an infectious disease resulting from use of the toy in its intended play modes (normal use) as well as unintended play modes (reasonably foreseeable abuse).

This document will not, nor is it intended to, eliminate parental or supervisor responsibility in the appropriate selection of toys. The requirements of this standard apply to toys in an as received state, it is expected that parents and supervisors will exercise due care in ensuring toys are clean and not contaminated after use. Nor will this document eliminate the need for parental supervision in situations where children of various ages have access to the same toy(s).

1 Scope

This document specifies microbiological cleanliness and preservative efficacy requirements for *accessible aqueous media* in toys.

The requirements in this document apply to all toys that are, contain or are supplied with *accessible* aqueous materials (e.g. paste, putty, liquid or gel).

The cleanliness and preservation effectiveness requirements are applicable to a toy as it is initially received by the consumer, in an unopened and undamaged container. This document does not apply to a toy that has been used, has had its packaging opened or is otherwise compromised in a way that would introduce microbiological contamination.

This document does not cover products and *samples* which are post-consumer use, since the microbiological limits are inappropriate given there is no way to establish what conditions the toys have been subject to before testing.

The following are specifically excluded from the scope of this document:

— materials that are inaccessible during normal use or reasonably foreseeable abuse;

— food;

— cosmetics;

— components of toys covered by EN 71-13 where;

  — the component is in scope of the Cosmetic Products Regulation (i.e. Regulation (EC) No 1223/2009 [13]; and

  — the component comprises only recognized food flavours and food ingredients (see relevant legislation, for example Regulation (EC) No 178/2002 [16] (“general food law”), Regulation (EC) No 1334/2008 [15] (flavours), Regulation (EC) No 1333/2008 [14], Commission Regulation (EU) No 231/2012 [18] (food additives) and Regulation (EU) No 1169/2011 (food information to consumers)[17]);

— experimental sets covered by EN 71-4.

NOTE Play cosmetics, that are only for use on the toy (e.g. makeup products only for a doll), are not excluded.

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 71-1:2014+A1:2018, *Safety of toys — Part 1: Mechanical and physical properties*

EN ISO 6222:1999, *Water quality — Enumeration of culturable micro-organisms — Colony count by inoculation in a nutrient agar culture medium (ISO 6222:1999)*

EN ISO 9308-1:2014[1], *Water quality — Enumeration of Escherichia coli and coliform bacteria — Part 1: Membrane filtration method for waters with low bacterial background flora (ISO 9308-1:2014)*

[1] As impacted by EN ISO 9308-1:2014/A1:2017

EN ISO 9308-2:2014, *Water quality — Enumeration of Escherichia coli and coliform bacteria — Part 2: Most probable number method (ISO 9308-2:2012)*

EN ISO 9308-3:1998[2], *Water quality — Detection and enumeration of Escherichia coli and coliform bacteria in surface and wastewater — Part 3: Miniaturized method (Most Probable Number) by inoculation in liquid medium (ISO 9308-3:1998)*

EN ISO 11930:2019[3], *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product (ISO 11930:2019)*

EN ISO 16212:2017[4], *Cosmetics — Microbiology — Enumeration of yeast and mould (ISO 16212:2017)*

EN ISO 18415:2017[5], *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms (ISO 18415:2017)*

EN ISO 18416:2015[6], *Cosmetics — Microbiology — Detection of Candida albicans (ISO 18416:2015, Corrected version 2016-12-15)*

EN ISO 21148:2017, *Cosmetics — Microbiology — General instructions for microbiological examination (ISO 21148:2017)*

EN ISO 21149:2017[7], *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria (ISO 21149:2017)*

EN ISO 21150:2015[8], *Cosmetics — Microbiology — Detection of Escherichia coli (ISO 21150:2015)*

EN ISO 22717:2015[9], *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa (ISO 22717:2015)*

EN ISO 22718:2015[10], *Cosmetics — Microbiology — Detection of Staphylococcus aureus (ISO 22718:2015)*

ISO 18787:2017, *Foodstuffs — Determination of water activity*

European Pharmacopoeia 11th edition, 2024

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/

[2] As impacted by EN ISO 9308-3:1998/AC:2000
[3] As impacted by EN ISO 11930:2019/A1:2022
[4] As impacted by EN ISO 16212:2017/A1:2022
[5] As impacted by EN ISO 18415:2017/A1:2022
[6] As impacted by EN ISO 18416:2015/A1:2022
[7] As impacted by EN ISO 21149:2017/A1:2022
[8] As impacted by EN ISO 21150:2015/A1:2022
[9] As impacted by EN ISO 22717:2015/A1:2022
[10] As impacted by EN ISO 22718:2015/A1:2022

3.1
accessible
contactable under the test conditions of 8.10 of EN 71-1:2014+A1:2018

3.2
aqueous media
toy material formulated with water and containing water in the finished product

Note 1 to entry: Formulated with water means the material has had water added during the manufacturing process and excludes materials that have absorbed water, unintentionally.

3.3
aerobic mesophilic microorganisms
aerobic bacteria, yeast and mould with optimal growth at temperatures between 20 °C and 40 °C

3.4
sample
portion of the product (at least 1 g or 1 ml) that is used in the test

3.5
total aerobic mesophilic count
TAMC
measure of *aerobic mesophilic microorganism* formation on culture media

3.6
total yeast and mould count
TYMC
measure of yeast and mould colony formation on culture media under aerobic conditions

4 General

When conducting microbiological tests, users of the standard shall ensure that:

— only those microorganisms which are present in the *samples* are isolated or enumerated;

— the microorganisms do not contaminate the environment.

In order to achieve this, users of the standard shall pay attention to sanitation and hygiene and shall use aseptic techniques which ensure, as far as possible, exclusion of contamination.

EXAMPLE A large number of manipulations could unintentionally lead to cross-contamination.

Users of this standard shall have a thorough knowledge of the microbiological testing techniques and of the microorganisms involved. Users of this standard shall verify the accuracy of the results given by their technique.

NOTE Potentially the most important control is the cleanliness of water used in the manufacturing process. Since a test standard cannot set requirements for a manufacturing process, information on good practice is given in the informative Annex B.