SLOVENSKI STANDARD
SIST EN 71-3:2013+A3:2018

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Varnost igrač - 3. del: Migracija določenih elementov (z dopolnili do vključno A3)

Safety of toys - Part 3: Migration of certain elements

Sicherheit von Spielzeug - Teil 3: Migration bestimmter Elemente

Sécurité des jouets - Partie 3: Migration de certains éléments

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97.200.50 Igrače Toys

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English Version

Safety of toys - Part 3: Migration of certain elements

Sécurité des jouets - Partie 3: Migration de certains éléments

Sicherheit von Spielzeug - Teil 3: Migration bestimmter Elemente

This European Standard was approved by CEN on 29 Mai 2013 and includes Amendment 1 approved by CEN on 18 August 2014, Amendment 2 approved by CEN on 18 April 2017 and Amendment 3 approved by CEN on 15 March 2018.

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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 71-3:2013+A3:2018) 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of an identical text or by endorsement, at the latest by December 2018, and conflicting national standards shall be withdrawn at the latest by December 2018.

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 supersedes A3 EN 71-3:2013+A2:2017 A3.

This document includes Amendment 1 approved by CEN on 2014-08-18.

This document includes Amendment 2 approved by CEN on 2017-04-18.

This document includes Amendment 3 approved by CEN on 2018-03-15.

The start and finish of text introduced or altered by amendments is indicated in the text by tags A1 A1, A2 A2 and A3 A3.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 2009/48/EC.

For relationship with EU Directive 2009/48/EC, see informative Annex ZA, which is an integral part of this document.

The significant changes from the previous edition of this standard are detailed in Annex A.

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 9: Organic chemical compounds — Requirements*;

— *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, gustative board games, cosmetic kits and gustative kits*;

— *Part 14: Trampolines for domestic use*.

NOTE 1 In addition to the above parts of EN 71, the following guidance documents have been published: CEN Technical Report CEN/TR 15071, *Safety of toys — National translations of warnings and instructions for use in* EN 71, CEN Technical Report CEN/TR 15371-1, Safety of toys - Interpretations - Part 1: Replies to requests for interpretation of EN 71-1, EN 71-2, EN 71-8 and EN 71-14 and CEN/TR 15371-2, Safety of toys - Interpretations - Part 2: Replies to requests for interpretation of the chemical standards in the EN 71-series.

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

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

Introduction

The Toy Safety Directive (2009/48/EC) [1] specifies maximum migration limits for three categories of *toy materials*. The limits for the migration of certain elements are expressed in milligram per kilogram *toy material* and are detailed in Table 2. The purpose of the limits is to minimize children's exposure to certain potentially toxic elements.

1 Scope

This European Standard specifies requirements and test methods for the migration of aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin and zinc from *toy materials* and from parts of toys.

Packaging materials are not considered to be part of the toy unless they have intended play value.

NOTE 1 See guidance document of the European Commission guidance document no. 12 [2] on the application of the Directive on the safety of toys – packaging.

The standard contains requirements for the migration of certain elements from the following categories of *toy materials*:

— Category I: Dry, brittle, powder like or pliable materials;

— Category II: Liquid or sticky materials;

— Category III: Scraped-off materials.

The requirements of this standard do not apply to toys or parts of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking or swallowing or prolonged skin contact when the toy or part of toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children.

NOTE 2 For the purposes of this standard, for the following toys and parts of toys the likelihood of sucking, licking or swallowing toys is considered significant (see H.2 and H.3):

— all toys intended to be put in the mouth or to the mouth, cosmetics toys and writing instruments categorized as toys can be considered to be sucked, licked or swallowed;

— all the accessible parts and components of toys intended for children up to 6 years of age can be considered to come into contact with the mouth. The likelihood of mouth contact with parts of toys intended for older children is not considered significant in most cases (see H.2).

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 71-1:2011, *Safety of toys — Part 1: Mechanical and physical properties*

EN ISO 3696, *Water for analytical laboratory use - Specification and test methods (ISO 3696)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
base material
material upon which *coatings* may be formed or deposited

3.2
coating
layer of material formed or deposited on a *base material* which can be removed by *scraping*

Note 1 to entry: *Coatings* can include paints, varnishes, lacquers, inks, polymeric *coatings* or other substances of a similar nature, whether they contain metallic particles or not, and irrespective of the manner of application.

3.3
limit of detection
minimum single result which, with a stated probability, can be distinguished from a suitable blank value; the result, c_L, is given by the formula:

$$c_L = \bar{x}_{bl} + k \times s_{bl}$$

where

$\bar{x}_{bl}$ is the mean of the blank values,

s_{bl} is the standard deviation of the blank values and

k is a numerical factor chosen according to the confidence level desired

Note 1 to entry: The use of $k = 3$ will usually suffice.

3.4
limit of quantification
lowest amount of analyte in a sample that can be quantitatively determined with a suitable precision and accuracy

Note 1 to entry: For the purpose of this standard, the limit of quantification is twice the limit of detection.

3.5
other material, whether mass coloured or not
material such as wood, leather or other porous substances which may absorb colouring matter without forming a *coating*

3.6
paper
sheet formed by irregularly intervened fibres with a mass per unit area of 400 g/m^2 or less

3.7
paper board
sheet formed by irregularly intervened fibres with a mass per unit area over 400 g/m^2

Note 1 to entry: The term *paperboard* also includes materials commonly referred to as card or cardboard with a mass per unit area over 400 g/m^2.

3.8
scraping
mechanical removal of *coatings* down to but not including the *base material*

3.9
toy material
material present in toys and accessible as determined in accordance with EN 71-1:2011, 8.10

4 Requirements

4.1 Toy material categories (see H.4)

Table 1 shows the categories of common *toy materials*. Toys not listed in Table 1 shall be classified into one of the categories.

Table 1 — Cross-reference table for determining category

Toy Material	Category I	Category II	Category III
Coatings of paints, varnishes, lacquers, printing inks, polymers, foams and similar *coatings*			X
Polymeric and similar materials, including laminates, whether textile reinforced or not, but excluding other textiles			X
Paper and paper board			X
Textiles, whether natural or synthetic			X
Glass, ceramic, metallic materials			X
Other materials whether mass coloured or not (e.g. wood, fibre board, hard board, bone and leather)			X
Compressed paint tablets, materials intended to leave a trace or similar materials in solid form appearing as such in the toy (e.g. the cores of colouring pencils, chalk, crayons)	X		
Pliable modelling materials, including modelling clays and plaster [3]	X		
Liquid paints, including finger paints, varnishes, lacquers, liquid ink in pens and similar materials in liquid form appearing as such in the toy (e.g. slimes, bubble solution)		X	
Glue sticks		X	

4.2 Specific requirements

The migration of elements from *toy materials* categorized in accordance with 4.1 shall not exceed the migration limits given in Table 2 when tested in accordance with Clauses 7 and 8.

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Table 2 — Migration limits from toy materials

Element	Migration limit		
	Category I mg/kg	Category II mg/kg	Category III mg/kg
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18 750
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	2,0	0,5	23
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

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5 Principle

Soluble elements are extracted from *toy materials* using conditions which simulate the material remaining in contact with gastric juices for a period of time after swallowing. The concentrations of the soluble elements are determined quantitatively by three different methods:

— method for determining general elements: Aluminium, Antimony, Arsenic, Barium, Boron, Cadmium, Chromium, Cobalt, Copper, Lead, Manganese, Mercury, Nickel, Selenium, Strontium, Tin and Zinc;

— method for determining Chromium (III) and Chromium (VI);

— method for determining organic tin.

6 Reagents and apparatus

6.1 Reagents

All reagents used for analysis shall be of analytical grade or, if unavailable, technical grade reagents which have been determined to have acceptably low levels of impurity to allow the analysis to be performed.

6.1.1 Hydrochloric acid solution, c(HCl) = (0,07 ± 0,005) mol/l.

6.1.2 Hydrochloric acid solution, c(HCl) = (0,14 ± 0,010) mol/l.

6.1.3 Hydrochloric acid solution, c(HCl) = approximately 1 mol/l.

6.1.4 Hydrochloric acid solution, c(HCl) = approximately 2 mol/l.

6.1.5 Hydrochloric acid solution, c(HCl) = approximately 6 mol/l.

6.1.6 n-Heptane, (C_7H_{16}), 99 %.

6.1.7 Water, of at least grade 3 purity in accordance with EN ISO 3696.

6.2 Apparatus

Standard laboratory equipment and the following shall be used.

6.2.1 Plain weave wire cloth stainless steel sieve, of nominal aperture size 0,5 mm and tolerances as indicated in Table C.1.

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6.2.2 Equipment for measuring pH, calibrated and sufficiently accurate for the purposes of this European Standard. A1

6.2.3 Centrifuge, capable of centrifuging at high speed to separate the solids.

6.2.4 A means to agitate the mixture, at a temperature of (37 ± 2) °C.

An orbital or linear shaker, wrist action shaker, shaking water bath or magnetic stirrer can be used. It is important that the migration solution is in constant motion relative to the sample.

6.2.5 A selection of containers of gross volume, between 1,6 times and 5,0 times that of the volume of hydrochloric acid extract.

NOTE It is important to be aware the use of borosilicate glass ware may result in high blank values for Boron.

6.2.6 High retention filter-paper, ashless filter paper, particle retention in liquids 2,5 µm.

6.2.7 Membrane filters with pore sizes of 0,45 µm, 0,22 µm and 0,02 µm.

7 Sampling and sample preparation

7.1 Selection of test portions

A laboratory sample for testing shall consist of one toy in the form in which it will be marketed. Test portions shall be taken from *toy materials* of the single toy sample. Identical materials in the toy may be combined and treated as a single test portion but additional toy samples shall not be used to prepare larger test portions. Test portions are taken from each colour of each *toy material*. Test portions may be composed of more than one *toy material* or colour only when discrete specimens cannot be separated physically, e.g. dot printing, patterned textiles, etc.

NOTE This requirement does not preclude the preparation of test portions which represent the material and any *base material* upon which it is deposited.

If the total weight of available *toy material* is less than 10 mg test portions are disregarded (see H.5).

The above does not preclude the possibility of testing *toy materials* before they are used to manufacture a toy in order to prove compliance of the final toy. In this case, it shall be assessed that the manufacturing process does not influence the migration of elements from the *toy materials*.

7.2 Standards preparation

Prepare standard solutions covering a suitable working range appropriate to the required limits for each element for the three categories. Examples for ICP-MS and ICP-OES are included in Annex E.

7.3 Sample preparation

7.3.1 General

A blank solution shall be determined for any bias. The analytical results shall be corrected for any bias due, for example, to contaminants present in the filter paper (6.2.6) or the gastric simulant.

When there is a significant bias the method should be checked.

7.3.2 Category I: Dry, brittle, powder like or pliable and Category II: Liquid or sticky

If possible obtain a test portion of not less than 100 mg of the material from the laboratory sample.

If a test portion of 100 mg or more cannot be obtained, a test portion shall be obtained from each toy material present in the laboratory sample in a mass greater than 10 mg. If the weight of the test portion obtained is between 10 mg and 100 mg, that weight shall be reported (see Clause 10 h)). In this case the analytical results shall be calculated as though 100 mg of the test portion had been used (see H.5).

If the toy material contains any grease, oil, wax or similar material, material shall be de-waxed. De-waxing shall not be carried out on test portions being analysed for organic tin. Dry a high retention filter paper (see 6.2.6) for 4 h at 37 °C ± 4°C. Weigh the filter paper to the nearest 0,1 mg (Wfp1). The filter paper used should be as small as possible without risking loss of the test portion during the de-waxing procedure. Weigh the test portion, to the nearest 0,1 mg, onto the pre-dried and weighed filter paper. Calculate the mass of the test portion. Use this mass for the calculation of the results of the test. Fold the filter paper carefully to enclose the test portion without loss. Extract the test portion within the filter paper with boiling n-heptane (6.2.5) using suitable laboratory apparatus. The use of a de-waxing step shall be reported (see Clause 10 h)).

It has been shown that Soxhlet extraction with n-heptane for 6 h is usually sufficient to completely remove non-polar ingredients from waxy toy materials. Alternative methods should be validated to show that they are capable of completely removing the non-polar ingredients from relevant toy materials.

After removal of non-polar ingredients, dry the folded filter paper containing the dewaxed test portion in an oven at (37 ± 2) °C for 4 h to ensure the removal of residual solvent. Weigh the dried filter paper parcel, to the nearest 0,1 mg (Wfp2). Use Wfp2 for the calculation under 7.4.2.1 on the volume of 0,07 M HCl.

7.3.3 Category III: Scraped-off

7.3.3.1 *Coatings* of paint, varnish, lacquer, printing ink, polymer and similar *coatings*

Remove the *coating* from the laboratory sample by mechanical means (usually *scraping*) at room temperature. If possible obtain a test portion of not less than 100 mg passing through a metal sieve of aperture 0,5 mm (see 6.2.1).

If the weight of the test portion obtained is between 10 mg and 100 mg, that weight shall be reported (see Clause 10 h)). In this case the analytical results shall be calculated as though 100 mg of the test portion had been used (see H.5). When possible, *coatings* on textiles are to be scraped off as a powder (and report this under Clause 10 h)). In case of a thick layer or one which is difficult to remove (e.g. pliable or plasticised layers), the *coating* can be cut off and tested as polymeric material (7.3.3.2).

7.3.3.2 Polymeric and similar materials including laminates and reinforced textiles, but excluding other textiles

If possible obtain a test portion of not less than 100 mg of the polymeric or similar material, according to the following directions.

Cut out test portions from the areas having the thinnest material cross section. Each test piece shall have at least one dimension of approximately 6 mm when possible (see H.6). The use of pre-prepared reference materials for visual size comparison is recommended.

If a test portion of 100 mg or more cannot be obtained, a test portion shall be obtained from each *toy material* present in the laboratory sample in a mass greater than 10 mg. If the weight of the test portion obtained is between 10 mg and 100 mg, that weight shall be reported (see Clause 10 h)). In this case the analytical results shall be calculated as though 100 mg of the test portion had been used (see H.5).

7.3.3.3 *Paper* and *paper board*

If possible obtain a test portion of not less than 100 mg of the *paper* or *paper board*. Each test piece shall have at least one dimension of approximately 6 mm when possible (see H.6). The use of pre-prepared reference materials for visual size comparison is recommended.

If a test portion of 100 mg or more cannot be obtained, a test portion shall be obtained from each *toy material* present in the laboratory sample in a mass greater than 10 mg. If the weight of the test portion obtained is between 10 mg and 100 mg, that weight shall be reported (see Clause 10 h)). In this case the analytical results shall be calculated as though 100 mg of the test portion had been used (see H.5).

If the *paper or paper board* to be tested has paint, varnish, lacquer, printing ink, adhesive or similar material applied to its surface, test portions of the *coating* shall not be taken separately. In such cases test portions shall be taken from the *toy material* so that they also include representative parts of the coated area.

7.3.3.4 Textiles, whether natural or synthetic (see H.7)

If possible obtain a test portion of not less than 100 mg of the textile material by cutting into test pieces.

Each test piece shall have at least one dimension of approximately 6 mm when possible (see H.6). The use of pre-prepared reference materials for visual size comparison is recommended.