

Varnost igrač - 3.del: Migracija določenih elementov

Safety of toys - Part 3: Migration of certain elements

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EUROPEAN STANDARD

EN 71-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Descriptors: Toys, safety requirements, accident prevention, children, materials, toxicity, tests, determination, migrations, metals

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 1994-12-13. 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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

FOREWORD

This European Standard was prepared by CEN/TC 52 "Safety of toys", of which the secretariat is held by DS.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

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of an identical text or by endorsement, at the latest by June 1995, and conflicting national standards shall be withdrawn at the latest by June 1995.

This standard constitutes the third part of the European Standard on "Safety of toys".

This part should be read in conjunction with part 1.

This standard specifies requirements and test methods for the migration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy material.

This standard contains 4 annexes:

- Annex A (normative) - Test method to determine acidity of 1,1,1-trichloroethane,
- Annex B (normative) - Sieve requirements,
- Annex C (informative) - Preparation and analysis of test portions,
- Annex D (informative) - Background and rationale for the requirements and test methods.

This standard is the result of the revision of EN 71-3:1988.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

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INTRODUCTION

This European Standard for 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 6: Graphical symbol for age warning labelling.

This standard is Part 3 of the European Standard on Safety of Toys, EN 71.

The requirements of this standard are based on bioavailability resulting from the use of toys and should not as an objective exceed the below mentioned levels per day:

- 0,2 μg for antimony;
- 0,1 μg for arsenic;
- 25,0 μg for barium;
- 0,6 μg for cadmium;
- 0,3 μg for chromium;
- 0,7 μg for lead;
- 0,5 μg for mercury;
- 5,0 μg for selenium.

For the interpretation of these figures it has been necessary to identify an upper limit for the ingestion of toy material. Very limited data have been available for identifying this upper limit. As a working hypothesis, a summed average daily intake for the various toy materials has been gauged at the currently accepted figure of 8 mg/day, being aware that in certain individual cases these figures might be exceeded.

Combining the daily intake with the bioavailability figures listed above, limits are obtained for various toxic elements in microgram per gram (milligram per kilogram) and are detailed in Table 1. The figures obtained have been adjusted to minimize children's exposure to toxic elements and to ensure analytical feasibility taking into account limits achievable under current manufacturing conditions. (See annex D).

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1 Scope

This Part of this European Standard specifies requirements and test methods for the migration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and from parts of toys except materials not accessible (see Part 1 of this standard).

Packaging materials are not included unless they are part of the toy or have intended play value. (See annex D)

When appropriate, the toy is subjected to relevant tests, specified in Part 1 of this standard, before the accessibility is considered.

Requirements are included for the migration from the following toy materials:

- coatings of paints, varnishes, lacquers, printing inks, polymers and similar coatings (see 8.1);
- polymeric and similar materials, including laminates, whether textile reinforced or not, but excluding other textiles (see 8.2);
- paper and paper board (see 8.3);
- textiles, whether natural or synthetic (see 8.4);
- glass/ceramic/metallic materials (see 8.5);
- other materials whether mass coloured or not (e.g. wood, fibre board, hard board, bone and leather) (see 8.6);
- materials intended to leave a trace (e.g. the graphite materials in pencils and liquid ink in pens) (see 8.7);
- pliable modelling materials, including modelling clays, and gels (see 8.8);
- paints, including finger paints, varnishes, lacquers, glazing powders and similar materials in solid or in liquid form appearing as such in the toy (see 8.9).

Toys and parts of toys which, due to their accessibility, function, mass, size or other characteristics, obviously exclude any hazard due to sucking, licking or swallowing, bearing in mind the normal and foreseeable behaviour of children, are not covered by this Part of EN 71.

NOTE: For the purposes of this standard, the following criteria are considered appropriate in the categorisation of sucking, licking or swallowing:

- all intended food/oral contact toys, cosmetic toys and writing instruments categorised as toys;
- toys intended for children up to 6 years of age, i.e. all accessible parts and components where there is a probability that those parts or components may come into contact with the mouth. (See annex D)

2 Normative references

This standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 71-1	Safety of toys - Part 1: Mechanical and physical properties
ISO 3696	Water for analytical laboratory use - Specification and test methods

3 Definitions

For the purposes of this standard the following definitions apply:

3.1 base material: Material upon which coatings may be formed or deposited.

3.2 coating: All layers of material formed or deposited on the base material or toy and includes paints, varnishes, lacquers, inks, polymers or other substances of a similar nature, whether they contain metallic particles or not, of a similar nature no matter how it has been applied to the toy and which can be removed by scraping with a sharp blade.

3.3 detection limit of a method: Three times the standard deviation of the blank value.

3.4 other materials, whether mass coloured or not: Materials such as wood, leather and other porous substances which may absorb colouring matter without forming a coating.

3.5 paper and paper board: A maximum mass per unit area of 400 g/m² is the limit for treating material under this category. Above this mass per unit area the substance is treated as "other material" and may be fibre board or hard board etc.

3.6 scraping: Mechanical removal of coatings down to the base material.

3.7 toy material: All the accessible materials present in toys.

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4 Requirements

4.1 Specific requirements

The migration of elements from toys and parts of toys as specified in clause 1 shall comply with the limits given in Table 1 when tested in accordance with clauses 7, 8 and 9. This requirement does not apply to lead solder when used for electric connections. (See annex D).

Table 1: Limits of element migration from toy materials

Element		Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Maximum migrated element in mg/kg toy material	Any toy material given in clause 1 except for: - modelling clay - finger paint	60	25	1000	75	60	90	60	500
	Modelling clay and finger paint	60	25	250	50	25	90	25	500

Table 2: Analytical correction

Element	Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Analytical correction (in %)	60	60	30	30	30	30	50	60

4.2 Interpretation of results

The analytical results of materials established in clauses 7, 8 and 9 shall be adjusted by subtracting the analytical correction in table 2 to obtain an adjusted analytical result.

Materials are deemed to comply with the requirements of this standard if the adjusted analytical result is less than or equal to the limits in table 1 (See annex D).

NOTE: Due to the precision of the methods specified in this standard an adjusted analytical result is required to take into consideration the results of interlaboratory trials (See annex D).

EXAMPLE: Analytical result of lead 120 mg/kg

Analytical correction from table 2: 30 %

$$\text{Adjusted analytical result} = 120 - \frac{120 \times 30}{100} = 120 - 36$$

Adjusted analytical result = 84 mg/kg. This is deemed as complying with the requirements of the standard. (Lead 90 mg/kg).

5 Principle

Soluble elements are extracted from toy materials under the conditions which simulate the material remaining in contact with stomach acid for a period of time after swallowing. The concentrations of the soluble elements are determined quantitatively.

6 Reagents and apparatus

NOTE: No recommendation is made for the reagents, materials, and apparatus necessary for carrying out the analytical tests specified in clause 9.

6.1 Reagents

During the analyses, use only reagents of recognised analytical grade. (See annex D).

6.1.1 Hydrochloric acid solution $c(\text{HCl}) = (0,07 \pm 0,005) \text{ mol/l}$

6.1.2 Hydrochloric acid solution $c(\text{HCl}) = (0,14 \pm 0,010) \text{ mol/l}$

6.1.3 Hydrochloric acid solution $c(\text{HCl}) = \text{approximately } 1 \text{ mol/l}$

6.1.4 Hydrochloric acid solution $c(\text{HCl}) = \text{approximately } 2 \text{ mol/l}$

6.1.5 Hydrochloric acid solution $c(\text{HCl}) = \text{approximately } 6 \text{ mol/l}$

6.1.6 1,1,1-trichloroethane containing a maximum of 10 mg/kg of hydrochloric acid when tested in accordance with annex A, or other suitable solvents. (See annex D).

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

6.2 Apparatus

Normal laboratory apparatus and

6.2.1 Plain weave wire cloth stainless steel metal sieve of nominal aperture size 0,5 mm and tolerances as indicated in table B.1 in annex B.

6.2.2 A means of measuring pH with an accuracy of $\pm 0,2$ pH units. Cross-contamination shall be prevented. (See annex D).

6.2.3 Membrane filter with a pore size of $0,45 \mu\text{m}$.

6.2.4 Centrifuge capable of centrifuging at $(5000 \pm 500) g^{1)}$. (See annex D).

6.2.5 A means to agitate the mixture at a temperature of $(37 \pm 2) ^\circ\text{C}$.

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

¹⁾ $g = 9,80665 \text{ m/s}^2$

7 Selection of test portions

A laboratory sample for testing shall consist of a toy either in the form in which it is marketed, or in the form in which it is intended to be marketed. Test portions shall be taken from accessible parts (see EN 71-1) of a single toy sample, i.e. identical materials in the toy may be combined and treated as a single test portion but additional toy samples shall not be used. Test portions are only permitted to be composed of more than one material or colour where physical separation e.g. dot printing, patterned textiles or mass limitation reasons, precludes the formation of discrete specimens. (See annex D).

NOTE: The requirement does not preclude that test portions can be taken from materials in a form such that they are representative of the relevant material specified above and the substrate upon which they are deposited. (See annex D).

Test portions where less than 10 mg of material are available are not tested.

8 Preparation and analysis of test portions

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

8.1.1 Sample removal/preparation procedure

Remove the coating from the laboratory sample by mechanical means at room temperature and comminute it at a temperature not exceeding ambient. Obtain a test portion of not less than 100 mg passing through a metal sieve of aperture 0,5 mm (see 6.2.1).

Where there is only between 10 mg and 100 mg of comminuted uniform coating available this shall be tested in accordance with 8.1.2 and the quantity of the appropriate elements shall be calculated as if 100 mg of test portion had been used and the mass of the test portion shall be reported under 10 e).

In the case of coatings that by their nature cannot be comminuted (e.g. elastic/plastic paint) remove a test portion from the laboratory sample without comminuting the coating.

8.1.2 Test procedure

Using the appropriate sized container (see 6.2.6), mix the test portion so prepared with 50 times its mass of an aqueous solution at $(37 \pm 2)^\circ\text{C}$ of $c(\text{HCl}) = 0,07 \text{ mol/l}$ (see 6.1.1). Where the test portion has a mass of between 10 mg and 100 mg, mix the test portion with 5,0 ml of this solution at $(37 \pm 2)^\circ\text{C}$. Shake for 1 min. Check the acidity of the mixture. If the pH is greater than 1,5 add dropwise, while shaking the mixture, an aqueous solution of $c(\text{HCl})$ approximately 2 mol/l (see 6.1.4) until the pH is between 1,0 and 1,5. Protect the mixture from light. Agitate the mixture at $(37 \pm 2)^\circ\text{C}$ (see 6.2.5) for 1 h continuously and then allow to stand for 1 h at $(37 \pm 2)^\circ\text{C}$.

Without delay, efficiently separate the solids from the solution, firstly by filtration using a membrane filter (see 6.2.3), and if necessary, by centrifuging at up to $5000 g^{11}$ (see 6.2.4). Separation shall be completed as soon as possible after the completion of the standing time; centrifuging shall take no longer than 10 min and shall be reported under 10 e).

If the resulting solutions are to be kept for more than the working day prior to analysis they shall be stabilised by addition of hydrochloric acid so that the concentration of the stored solution is approximately $c(\text{HCl}) = 1 \text{ mol/l}$.

8.2 Polymeric and similar materials including laminates, whether reinforced textile or not, but excluding other textiles

8.2.1 Sample removal/preparation procedure

Obtain a test portion of not less than 100 mg of the polymeric or similar materials, whilst avoiding heating of the materials, according to the following directions:

Cut out test portions from the areas having the thinnest material cross section in order to ensure a surface area of the test pieces as large as possible in proportion to their mass. Each test piece shall in the uncompressed condition have no dimension greater than 6 mm.

If the laboratory sample is not uniform in its material, a test portion shall be obtained from each different material forming a mass greater than 10 mg. In the case where there is between 10 mg and 100 mg of uniform material the mass of the test portion shall be reported under 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used.

8.2.2 Test procedure

Follow the procedure in 8.1.2.

8.3 Paper and paper board

8.3.1 Sample removal/preparation procedure

Obtain a test portion of not less than 100 mg of the paper or paper board.

If the laboratory sample is not uniform in its material, a test portion shall be obtained from each different material forming a mass of not less than 100 mg. Where there is between 10 mg and 100 mg of uniform material the mass of the test portion shall be reported under 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used.

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If the paper or paper board to be tested is coated with a coating of paint, varnish, lacquer, printing ink, adhesive or similar coating, test portions of the coating shall not be taken separately. In such cases test portions shall be taken from the material in accordance with this subclause in a way that they also include representative parts of the coated area. Test portions so obtained shall be tested in accordance with relevant methods specified in this subclause and this shall be reported under 10 e). (See annex D).

¹¹ $g = 9,80665 \text{ m/s}^2$