

	<b>Safety of toys</b> Part 3: Migration of certain elements (includes Amendment A1 : 2000 + Corrigendum AC : 2002) English version of DIN EN 71-3 + A1 : 2000 + AC : 2002	<b>DIN</b> <b>EN 71-3</b>
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ICS 97.200.50

Sicherheitsnorm  
November 2000

Supersedes  
October 2000 edition.

Sicherheit von Spielzeug – Teil 3: Migration bestimmter Elemente  
(enthält Änderung A1 : 2000 + Berichtigung AC : 2002)

**European Standard EN 71-3 : 1994 + Amendment A1 : 2000 + Corrigendum AC : 2002  
has the status of a DIN Standard.**

*A comma is used as the decimal marker.*

**National foreword**

This standard has been prepared by CEN/TC 52 'Safety of toys' (Secretariat: Denmark).  
The responsible German body involved in its preparation was the *Normenausschuss Gebrauchstauglichkeit und Dienstleistungen* (Usability, Performance and Services Standards Committee), Technical Committee *Migration bestimmter Elemente*.  
DIN ISO 3696 is the standard corresponding to International Standard ISO 3696 referred to in clause 2 of the EN.


**Amendments**

This standard differs from the October 2000 edition as follows:

- a) Finger paints are no longer covered by the standard (now dealt with in DIN EN 71-7).
- b) Indication of the solvent used for removing grease, oil, wax or similar ingredients in toy materials is no longer required.
- c) Some printing errors have been corrected.

**Previous editions**

DIN EN 71-3: 1983-08, 1989-07, 1995-03, 2000-10.



EN comprises 15 pages.

**EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM**

**EN 71-3**  
December 1994  
+ A1  
April 2000  
+ AC  
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ICS 97.200.50

Supersedes EN 71-3 : 2000.

**English version**

**Safety of toys**

**Part 3: Migration of certain elements**

**(includes Amendment A1 : 2000 + Corrigendum AC : 2002)**

Sécurité des jouets – Partie 3: Migration de certains éléments  
(amendement A1 : 2000 + corrigendum AC : 2002 inclus)

Sicherheit von Spielzeug – Teil 3: Migration bestimmter Elemente  
(enthält Änderung A1 : 2000 + Berichtigung AC : 2002)

This European Standard was approved by CEN on 1994-12-13, Amendment A1 on 2000-03-11 and Corrigendum AC : 2002 on 2002-07-24.

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**CEN**

European Committee for Standardization

Comité Européen de Normalisation

Europäisches Komitee für Normung

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## Foreword to EN 71-3 : 1994

This European Standard has been prepared by CEN/TC 52 'Safety of toys', the Secretariat of which 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 the relevant EC Directive.

This part should be read in conjunction with Part 1.

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

This standard contains the following annexes:

- Annex A (normative) – Requirements for sieves
- Annex B (informative) – Preparation and analysis of test portions
- Annex C (informative) – Background and rationale for requirements and test methods

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

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement and conflicting national standards withdrawn, by June 1995 at the latest.

In accordance with 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, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

## Foreword to EN 71-3 : 1994/A1 : 2000

This amendment to EN 71-3 : 1994 has been prepared by Technical Committee CEN/TC 52 'Safety of toys', the Secretariat of which is held by DS.

This amendment has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of the relevant EU Directive. For relationship with this EU Directive, see Annex ZA.

This amendment shall be given the status of a national standard, either by publication of an identical text or by endorsement and conflicting national standards withdrawn, by October 2000 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

## Introduction

This European Standard 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.

The requirements of this standard are based on bioavailability resulting from the use of toys and should not exceed the following levels per day:

- 0.2 µg for antimony;
- 0.1 µg for arsenic;
- 25 µg for barium;
- 0.6 µg for cadmium;
- 0.3 µg for chromium;
- 0.7 µg for lead;
- 0.5 µg for mercury;
- 5 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, although in certain cases these figures might be exceeded.

Combining the daily intake with the bioavailability figures listed above, limits are obtained for various toxic elements in micrograms per gram (or milligrams 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 C).

## 1 Scope

This Part of this European Standard specifies requirements and test methods regarding the migration of antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and from parts of toys, except materials that are 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 C).

Where appropriate, the toy is subjected to relevant tests as 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 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, fibreboard, hardboard, 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, 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 categorization of sucking, licking or swallowing:

- all intended food oral contact toys, cosmetic toys and writing instruments categorized as toys;
- toys intended for children up to six years of age, i.e. all accessible parts and components for which there is the probability that they may come into contact with the mouth (see Annex C).

## 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 : 1987 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, including paints, varnishes, lacquers, inks, polymers or other substances of a similar nature, whether they contain metallic particles or not, no matter how they have 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 likely to absorb colorants without forming a coating.

### 3.5 Paper and board

A maximum mass per unit area of 400 g/m<sup>2</sup> 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 fibreboard, hardboard, etc.

### 3.6 Scraping

Mechanical removal of coatings down to the base material.

### 3.7 Toy material

Any accessible material present in toys.

## 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 C).

**Table 1: Limits of element migration from toy materials**

Element		Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Maximum migrated element, in mg/kg of toy material	Any toy material given in clause 1 except for modelling clay	60	25	1 000	75	60	90	60	500
	Modelling clay	60	25	250	50	25	90	25	500

### 4.2 Interpretation of results

The analytical results of materials established as in clauses 7, 8, and 9 shall be adjusted by subtracting the analytical correction in table 2 to obtain a corrected 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 C).

**Table 2: Analytical correction**

Element	Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Analytical correction, as a percentage	60	60	30	30	30	30	50	60

NOTE: Given the precision of the methods specified in this standard, a corrected analytical result is required to allow for the results of interlaboratory tests (see Annex C).

EXAMPLE: Analytical result of lead 120 mg/kg

Analytical correction from table 2: 30 %

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

Corrected analytical result = 84 mg/kg. This is deemed to comply 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 recommendations are made for the reagents, materials, and equipment necessary for carrying out the tests specified in clause 9.

### 6.1 Reagents

During the analyses, only analytical grade reagents shall be used (see Annex C).

**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,  $c(\text{HCl}) = \text{about } 1 \text{ mol/l}$ .

**6.1.4** Hydrochloric acid solution,  $c(\text{HCl}) = \text{about } 2 \text{ mol/l}$ .

**6.1.5** Hydrochloric acid solution,  $c(\text{HCl}) = \text{about } 6 \text{ mol/l}$ .

**6.1.6** *n*-heptane,  $\text{C}_7\text{H}_{16}$ , 99 %.

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

## **6.2 Apparatus**

Standard laboratory equipment and the following shall be used.

**6.2.1 Plain weave, stainless steel wire cloth sieve**, of nominal aperture size 0,5 mm and subject to tolerances as indicated in table A.1.

**6.2.2 pH measuring device**, capable of being read to an accuracy of  $\pm 0,2$  pH units; cross-contamination shall be precluded (see Annex C).

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

**6.2.4 Centrifuge**, capable of centrifuging at  $(5000 \pm 500) \text{ g}$ <sup>1)</sup> (see Annex C).

**6.2.5 Device for agitating** the mixture at a temperature of  $(37 \pm 2) ^\circ\text{C}$ .

**6.2.6 Set of containers** of gross volume between 1,6 times and 5 times that of the volume of hydrochloric acid extractant.

## **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; 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 C).

NOTE: The requirement does not preclude that test portions can be taken from materials so as to be representative of the relevant material specified above and the substrate upon which they are deposited (see Annex C).

Test portions of than 10 mg of material shall not be 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 ambient 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 size 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 item 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 an appropriately sized container (see 6.2.6), mix the test portion so prepared with 50 times its mass of a 0,07 mol/l aqueous solution of hydrochloric acid at  $(37 \pm 2) ^\circ\text{C}$  (see 6.1.1). Where the test portion has a mass of between 10 mg and 100 mg, mix the test portion with 5 ml of this solution at  $(37 \pm 2) ^\circ\text{C}$ . Shake for one minute. Check the acidity of the mixture. If the pH is greater than 1,5 dropwise add, while shaking the mixture, an aqueous solution of hydrochloric acid of about 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  $(37 \pm 2) ^\circ\text{C}$ .

<sup>1)</sup>  $g = 9,80665 \text{ m/s}^2$ .

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<sup>1)</sup> (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 ten minutes and shall be reported under item 10 e).

If the resulting solutions are to be kept for more than the working day prior to analysis, they shall be stabilized by adding hydrochloric acid so that the concentration of the stored solution is about 1 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, in the uncompressed condition, shall 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 present in a mass of not less than 10 mg. Where there is between 10 mg and 100 mg of uniform material, the mass of the test portion shall be reported under item 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 described in 8.1.2.

## **8.3 Paper and board**

### **8.3.1 Sample removal/preparation procedure**

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

If the laboratory sample is not uniform, a test portion shall be obtained from each different material present in 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 item 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used.

If the paper or 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 so as to 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 item 10 e) (see Annex C).

### **8.3.2 Test procedure**

Macerate the test portion so prepared with 25 times its mass of water (see 6.1.7) at  $(37 \pm 2)^\circ\text{C}$  so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to the appropriately sized container (see 6.2.6). Add to the mixture a 0,14 mol/l aqueous solution of hydrochloric acid (see 6.1.2) at  $(37 \pm 2)^\circ\text{C}$  at 25 times the mass of the test portion.

Shake for one minute. Check the acidity of the mixture. If the pH is greater than 1,5, dropwise add, while shaking the mixture, an aqueous solution of hydrochloric acid of about 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, first by filtration using a membrane filter (see 6.2.3), and if necessary, by centrifuging at up to 5000 g<sup>1)</sup> (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 ten minutes and shall be reported under item 10 e).

If the resulting solutions are to be kept for more than the working day prior to the analysis, they shall be stabilized by adding hydrochloric acid so that the concentration of the stored solution is about 1 mol/l.

## **8.4 Textiles, whether natural or synthetic**

### **8.4.1 Sample removal/preparation procedure**

Obtain a test portion of not less than 100 mg of the textile material by cutting into test pieces which, in the uncompressed condition, have no dimensions greater than 6 mm (see Annex C).

If the sample is not uniform in its material or colour, a test portion shall be obtained from each different material present in a mass greater than 100 mg. A portion present in a mass between 10 mg and 100 mg shall form part of the test portion obtained from the main material.

Samples taken from patterned textiles shall be representative of the whole material (see Annex C).

<sup>1)</sup>  $g = 9,80665 \text{ m/s}^2$ .

#### 8.4.2 Test procedure

Follow the procedure described in 8.1.2.

### 8.5 Glass/ceramic/metallic materials

#### 8.5.1 Sample removal/preparation procedure

Toys and components shall first be subjected to the relevant tests in accordance with EN 71-1. If the toy or component fits entirely within the small parts cylinder and contains accessible glass, ceramic or metallic materials, then the toy or component shall be tested in accordance with 8.5.2 after removal of any coating in accordance with 8.1.1 (see Annex C).

NOTE: Toys and components that have no accessible glass, ceramic or metallic materials are not to be tested according to 8.5.2 (see Annex C).

#### 8.5.2 Test procedure

Place the toy or component in a 50 ml glass container of nominal height 60 mm and nominal diameter 40 mm. Add a sufficient volume of a 0,07 mol/l aqueous solution of hydrochloric acid (see 6.1.1) at  $(37 \pm 2)^\circ\text{C}$  to just cover the toy or component. Cover the container, protect the contents from light and allow the contents to stand for 2 h at  $(37 \pm 2)^\circ\text{C}$ .

NOTE: This type of container will take all components/toys that fit inside the small parts cylinder.

Without delay, efficiently separate the solids from the solution, firstly by decantation followed by filtration using a membrane filter (see 6.2.3), and if necessary, by centrifuging at up to  $5000\text{ g}^1$  (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 ten minutes and shall be reported under item 10 e).

If the resulting solutions are to be kept for more than 24 h prior to analysis they shall be stabilized by adding hydrochloric acid so that the concentration of the stored solution is about 1 mol/l.

### 8.6 Other materials, whether mass coloured or not (see Annex C)

#### 8.6.1 Sample removal/preparation procedures

Obtain a test portion of not less than 100 mg of the material according to 8.2.1, 8.3.1, 8.4.1 or 8.5.1, whichever is appropriate.

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

If the material to be tested is coated with a coating of paint, varnish, lacquer, printing ink or similar coating, follow the procedure described in 8.1.1.

#### 8.6.2 Test procedure

The materials shall be tested by the most appropriate method specified in 8.2.2, 8.3.2, 8.4.2 or 8.5.2. The method used shall be reported under item 10 e).

### 8.7 Materials intended to leave a trace

#### 8.7.1 Sample removal/preparation procedure for materials in solid form

Obtain a test portion of not less than 100 mg of the material by cutting into test pieces, which, in the uncompressed condition, shall have no dimensions greater than 6 mm.

A test portion shall be obtained from each different material intended to leave a trace, present in the laboratory sample in a mass greater than 10 mg. Where there is between 10 mg and 100 mg of material, the mass of the test portion shall be reported under item 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used. If the material contains any grease, oil, wax or similar material, the test portion shall be enclosed in hardened filter paper and these ingredients shall be removed with *n*-heptane or other suitable solvent by using solvent-extraction (see 6.1.6).

#### 8.7.2 Sample removal/preparation procedure for materials in liquid form

Obtain a test portion of not less than 100 mg of the material from the laboratory sample. The use of an appropriate solvent to facilitate obtaining a test portion is permitted.

A test portion shall be obtained from each different material intended to leave a trace, present in the laboratory sample in a mass greater than 10 mg. Where there is between 10 mg and 100 mg of material, the mass of the test portion shall be reported under item 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used. If the material is intended to solidify in normal use and contains grease, oil, wax or similar material, the test portion shall be allowed to solidify under normal use conditions and

<sup>1)</sup>  $g = 9,80665\text{ m/s}^2$ .



the resulting material shall be enclosed in hardened filter paper and the grease, oil, wax or similar material shall be removed with *n*-heptane or other suitable solvent by using solvent-extraction (see 6.1.6).

#### 8.7.3 Test procedure for samples not containing grease, oil, wax or similar material

Using the appropriately sized container (see 6.2.6), mix the test portion so prepared with 50 times its mass of a 0,07 mol/l aqueous solution at  $(37 \pm 2)^\circ\text{C}$  of hydrochloric acid (see 6.1.1). For a test portion mass of between 10 mg and 100 mg, mix the test portion with 5 ml of this solution at  $(37 \pm 2)^\circ\text{C}$ . Shake for one minute. Check the acidity of the mixture.

If the test portion contains large quantities of alkaline materials, generally in the form of calcium carbonate, adjust the pH to between 1,0 and 1,5 with 6 mol/l hydrochloric acid solution (see 6.1.5) in order to avoid overdilution. The amount of hydrochloric acid used in relation to the amount of solution shall be reported under item 10 e). If only small quantities of alkaline material are present and the pH of the mixture is greater than 1,5, dropwise add, while shaking the mixture, an aqueous solution of hydrochloric acid of about 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  $(37 \pm 2)^\circ\text{C}$ .

#### 8.7.4 Test procedure for samples containing grease, oil, wax or similar material

With the test portion remaining in the hardened filter paper, macerate the test portion so prepared with 25 times the mass of the original material with water (see 6.1.7) at  $(37 \pm 2)^\circ\text{C}$  so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to the appropriately sized container (see 6.2.6). Add to the mixture a 0,14 mol/l aqueous solution of hydrochloric acid (see 6.1.2) at  $(37 \pm 2)^\circ\text{C}$  of mass equal to 25 times the mass of the original test portion. In the case of a test portion mass of between 10 mg and 100 mg, macerate the test portion with 2,5 ml of water (see 6.1.7). Quantitatively transfer the mixture to the appropriately sized container (see 6.2.6). Add 2,5 ml of 0,14 mol/l hydrochloric acid (see 6.1.2) at  $(37 \pm 2)^\circ\text{C}$  to the mixture. Shake for one minute. Check the acidity of the mixture. If the test portion contains large quantities of alkaline materials, generally in the form of calcium carbonate, adjust the pH to between 1,0 and 1,5 with hydrochloric acid of about 6 mol/l (see 6.1.5) in order to avoid overdilution. The amount of hydrochloric acid used in relation to the amount of solution shall be reported under item 10 e).

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, dropwise add, while shaking the mixture, an aqueous hydrochloric acid solution of about 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  $(37 \pm 2)^\circ\text{C}$ .

NOTE: The volume of the 0,07 mol/l or 0,14 mol/l solution is to be calculated on the mass of the test portion prior to dewaxing.

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  $5000\text{ g}^1$ ) (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 ten minutes and shall be reported under item 10 e).

If the resulting solutions are to be kept for more than the working day prior to the analysis, they shall be stabilized by adding hydrochloric acid so that the concentration of the stored solution is about 1 mol/l.

### 8.8 Pliable modelling materials, including modelling clays, and gels

#### 8.8.1 Sample removal/preparation procedure

Obtain a test portion of not less than 100 mg of the material from the laboratory sample.

A test portion shall be obtained from each different material in the laboratory sample. If the material contains grease, oil, wax or similar material, the test portion shall be enclosed in hardened filter paper and these ingredients shall be removed with *n*-heptane or other suitable solvent by using solvent-extraction (see 6.1.6).

#### 8.8.2 Test procedure for samples not containing grease, oil, wax or similar material

Using the appropriately sized container (see 6.2.6), mix the test portion so prepared after breaking up of clay or doughy materials, if appropriate, with 50 times its mass of an aqueous solution at  $(37 \pm 2)^\circ\text{C}$  of 0,07 mol/l hydrochloric acid (see 6.1.1). Shake the mixture for one minute. Check the acidity of the mixture. If the test portion contains large quantities of alkaline materials, generally in the form of calcium carbonate, adjust the pH to between 1,0 and 1,5 with hydrochloric acid of about 6 mol/l (see 6.1.5) in order to avoid overdilution. The amount of hydrochloric acid used in relation to the amount of solution shall be reported under item 10 e). If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, dropwise add while shaking the mixture an aqueous solution of hydrochloric acid of about 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 and then allow to stand for 1 h at  $(37 \pm 2)^\circ\text{C}$ .

<sup>1)</sup>  $g = 9,80665\text{ m/s}^2$ .

### 8.8.3 Test procedure for samples containing grease, oil, wax or similar material

With the test portion remaining in the hardened filter paper, macerate the test portion so prepared with 25 times the mass of the original material with water (see 6.1.7) at  $(37 \pm 2)^\circ\text{C}$  so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to the appropriately sized container (see 6.2.6). Add to the mixture a 0,14 mol/l aqueous solution of hydrochloric acid (see 6.1.2) at  $(37 \pm 2)^\circ\text{C}$  of mass equal to 25 times the mass of the original test portion. Shake for one minute. Check the acidity of the mixture. If the test portion contains large quantities of alkaline materials, generally in the form of calcium carbonate, adjust the pH to between 1,0 and 1,5 with an aqueous solution of hydrochloric acid of about 6 mol/l (see 6.1.5) in order to avoid overdilution. The amount of hydrochloric acid used in relation to the amount of solution shall be reported under item 10 e). If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, dropwise add while shaking the mixture with an aqueous solution of hydrochloric acid of about 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 one hour and then allow to stand for one hour at  $(37 \pm 2)^\circ\text{C}$ .

NOTE: The volume of the 0,07 mol/l or 0,14 mol/l solution is to be calculated on the mass of the test portion prior to dewaxing.

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  $5000\text{ g}^1$  (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 ten minutes and shall be reported under item 10 e).

If the resulting solutions are to be kept for more than the working day prior to analysis, they shall be stabilized by adding hydrochloric acid so that the concentration of the stored solution is about 1 mol/l.

## 8.9 Paints, varnishes, lacquers, glazing powders and similar materials, in solid or in liquid form

### 8.9.1 Sample removal/preparation procedure for materials in solid form

Obtain a test portion of not less than 100 mg of the material, if appropriate, by scraping off the material or by cutting into test pieces which, in the uncompressed condition, shall have no dimensions greater than 6 mm.

A test portion shall be obtained from each different material present in the laboratory in a mass greater than 10 mg. Where there is between 10 mg and 100 mg of material, the mass of the test portion shall be reported under item 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used. If the material contains any grease, oil, wax or similar material, the test portion shall be enclosed in hardened filter paper, and these ingredients shall be removed with *n*-heptane or other suitable solvent by using solvent-extraction (see 6.1.6).

If the test portion is removed by scraping, comminute the test portion so that the material is capable of passing through a metal sieve of aperture size 0,5 mm (see 6.2.1).

### 8.9.2 Sample removal/preparation procedure for materials in liquid form

Obtain a test portion of not less than 100 mg of the material from the laboratory sample, the use of an appropriate solvent to facilitate obtaining a test portion being permitted.

A test portion shall be obtained from each different material present in the laboratory sample in a mass greater than 10 mg. In the case where there is between 10 mg and 100 mg of material, the mass of the test portion shall be reported under item 10 e) and the quantity of the appropriate elements shall be calculated as if 100 mg of the test portion had been used. If the material is intended to solidify in normal use and contains grease, oil, wax or similar material, the test portion shall be allowed to solidify under normal conditions of use and the resulting material shall be enclosed in hardened filter paper and the grease, oil, wax or similar material shall be removed with *n*-heptane or other suitable solvent by using solvent-extraction (see 6.1.6).

### 8.9.3 Test procedure for samples not containing grease, oil, wax or similar material

Follow the procedure described in 8.7.3.

### 8.9.4 Test procedure for samples containing grease, oil, wax or similar material

With the test portion remaining in the hardened filter paper, macerate the test portion so prepared with 25 times the mass of the original material with water (see 6.1.7) at  $(37 \pm 2)^\circ\text{C}$  so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to the appropriately sized container (see 6.2.6). Add to the mixture an aqueous solution of hydrochloric acid of 0,14 mol/l (see 6.1.2) at  $(37 \pm 2)^\circ\text{C}$  of mass equal to 25 times the mass of the original test portion. Shake for one minute. Check the acidity of the mixture. If the test portion contains large quantities of alkaline materials, generally in the form of calcium carbonate, adjust the pH to between 1,0 and 1,5 with hydrochloric acid of about 6 mol/l (see 6.1.5) in order to avoid overdilution. The amount of hydrochloric acid used in relation to the amount of solution shall be reported under item 10 e).

<sup>1)</sup>  $\text{g} = 9,80665\text{ m/s}^2$ .

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, dropwise add, while shaking the mixture, an aqueous solution of hydrochloric acid of about 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 one hour and then allow to stand for one hour at  $(37 \pm 2) ^\circ\text{C}$ .

NOTE: The volume of the 0,07 mol/l or 0,14 mol/l solution is to be calculated on the mass of the test portion prior to dewaxing.

Without delay, efficiently separate the solids from the solution, first by filtration using a membrane filter (see 6.2.3), and if necessary, by centrifuging at up to 5000 g<sup>1)</sup> (see 6.2.4). Separation shall be completed as soon as possible after completion of the standing time; centrifuging shall take no longer than ten minutes and shall be reported under item 10 e).

If the resulting solutions are to be kept for more than the working day prior to analysis they shall be stabilized by adding hydrochloric acid so that the concentration of the stored solution is about 1 mol/l.

## 9 Determining the quantity of migrated elements

For determining the quantity of elements given in clause 1, methods having a detection limit of a maximum of 1/10 of the values to be determined (see table 1) shall be applied. The detection limit (of a method) is deemed to be three times the standard deviation of the blank value as measured by the laboratory carrying out the analysis of the toy materials.

Laboratories deviating from this requirement shall report the detection limit under item 10 c).

## 10 Test report

The test report shall contain at least the following information:

- a) type and identification of the product and/or material tested;
- b) a reference to this European Standard (EN 71-3 : 1994);
- c) the techniques used for determining the quantity of each element and the detection limit if the limit is deviating from the requirements in clause 9;
- d) the results of testing, expressed as mg element per kg of material, stating that the result is related to the soluble element;
- e) details of the procedure used (from clause 8) to prepare the test portion (including, for example, whether the base material was incorporated, whether centrifuging was required to separate the solids from the solution prior to analysis, whether additional acid was required to lower the pH, whether the ratio of solid to acid extractant exceeds 1 : 50) and whether the specimen was adjusted to 1 mol/l for overnight storage;
- f) any departure, by agreement or otherwise, from the test procedure specified;
- g) date of test.

## Annex A (normative) Requirements for sieves

Table A.1: Sieve dimensions and tolerances

Dimensions in millimetres

Nominal aperture size	Nominal wire diameter in test sieve	Tolerances		
		Maximum deviation for size of an individual aperture	Tolerance for average aperture	Intermediate deviation (no more than 6 % of the apertures to exceed the nominal plus this figure)
0,500	0,315	+0,090	$\pm 0,018$	+0,054

<sup>1)</sup>  $g = 9,80665 \text{ m/s}^2$ .

## Annex B (informative)

### Preparation and analysis of test portions

The diagram given below is an indication of which procedure is to be used for the various toy materials.

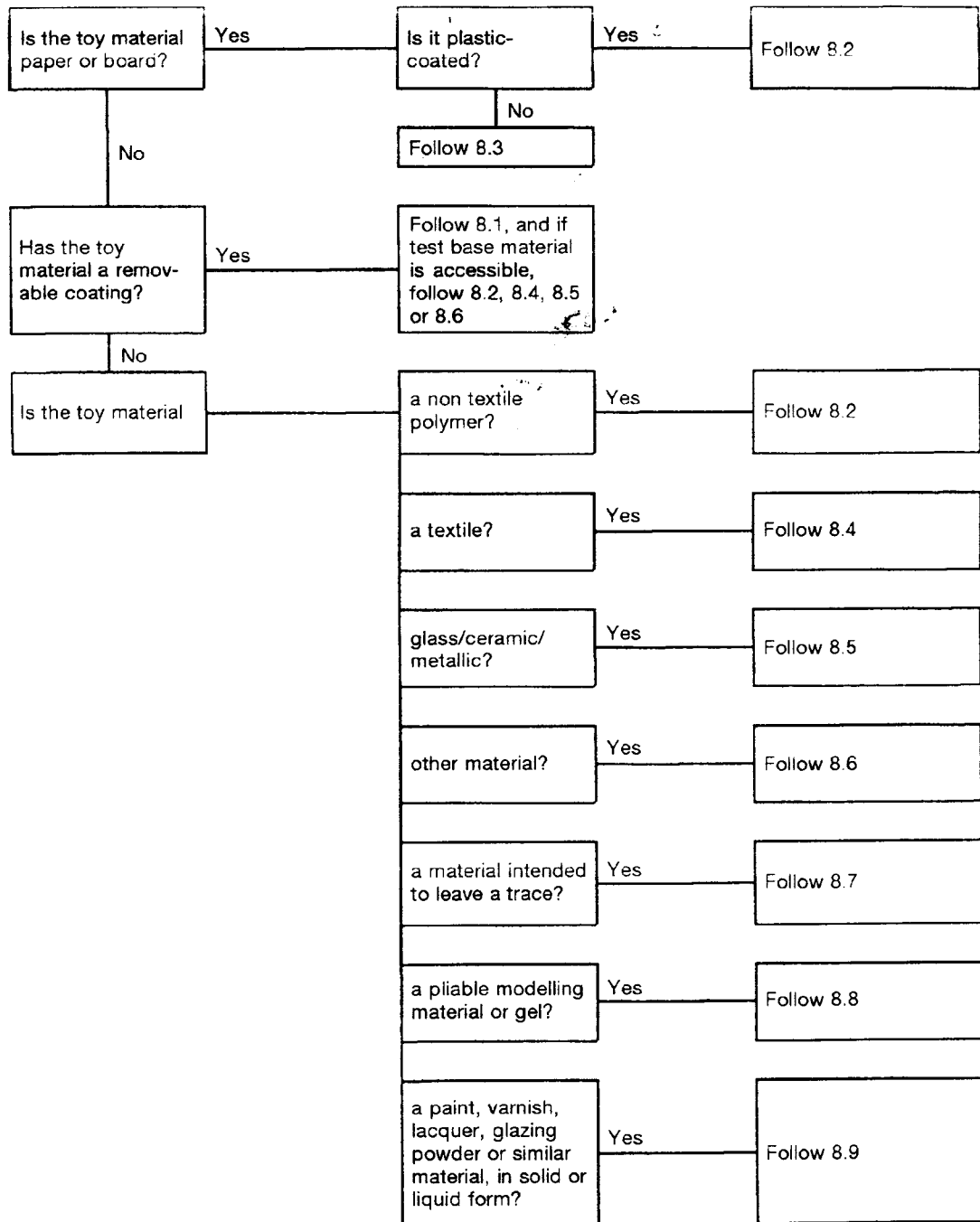


Figure C.1: Diagram showing the procedure and analysis of test portions

## Annex C (informative)

### Background and rationale for requirements and test methods specified in this Part of EN 71

#### C.1 Introduction

The way in which bioavailability is defined in the Toy Safety Directive<sup>2)</sup> led to the test methods in the standard addressing the amount of soluble element migration from a toy material.

The approach of total element determinations was discounted because of the following reasons:

- a) the Directive specified bioavailability limits and there has been no link to date between the availability of an element in a toy material with respect to extraction with simulated gastric solutions and the total element content of the material;
- b) in some cases such as barium sulfate, 2 % can be included in products to render them radio opaque; this use of barium would either have to be excluded from toys or a separate requirement made.

Cadmium compounds can be used as stabilizers in plastics such as polyvinylchloride (PVC). These compounds, under normal conditions, are insoluble in the simulated gastric solution. Therefore, if total elements were determined, its use would have to be accounted for in the requirements of the standard. A case can be made for selenium, which can be present as a constituent of insoluble pigments, etc. (cf. C.4).

#### C.2 Scope

##### C.2.1 Packaging

"Unless part of the toy" is suggested to mean, for example, boxes containing jigsaw puzzles or where the instructions are included on the packaging in the case of games, etc., but taking into account the 2nd indent of the Note in clause 1 restricting the requirements to cover toys intended for children up to 6 years of age. It is not intended to address, for example, blister packs containing simple instructions.

##### C.2.2 Note to clause 1

The Note is intended to indicate an approach to the decision of what toys, or toy components are excluded from the scope of the standard because of characteristics that render them unlikely to present a risk of injury by the ingestion of materials containing toxic elements.

This was considered a logical approach for a number of reasons including:

- as children get older, there is less of a tendency for them to place toy/toy materials in their mouths and therefore the risk presented by the ingestion of toxic elements is reduced;
- the larger the toy, or the less accessible the material, the risk of ingestion of toxic elements is diminished.

It was therefore considered that all toys intended to be placed in the mouth, or close to the mouth would be tested (e.g. pencils).

Toys intended for children over the age of six years were considered not to pose a significant risk of injury through the ingestion of toxic elements.

#### C.3 Specific requirements (see 4.1)

The limit of soluble barium has been raised from 500 mg/kg to 1 000 mg/kg for the following reasons:

- the use of barium sulfate in toys has led to levels of soluble barium in the extraction solution of  $c(\text{HCl}) = (0,07 \pm 0,005) \text{ mol/l}$  at 37 °C of between 400 mg/kg and 600 mg/kg as expressed on the mass of toy material taken; this level is such that, owing to the statistical uncertainty of results, a PASS or FAIL could not be indicated;
- the formation of non-bioavailable colloidal barium sulfate crystals in the filtrate resulting in levels of apparently soluble barium which exceed 500 mg/kg because of problems with filtration;
- in addition, the previous limit of migration of barium of 500 mg/kg from toy materials was not consistent with 25 µg/day bioavailability and the 8 mg/day of toy material intake; 25 µg corresponds to a migration limit of 3,125 mg/kg. It is understood that the 500 mg/kg limit was consciously selected despite the "theoretical" 3,125 mg/kg figure. The effect of the 500 mg/kg limit was to reduce the bioavailability from the advised 25 µg to 4 µg. It should be noted that the 25 µg figure has been reduced from an initial 50 µg, not for toxicological reasons, but according to the Commission of the European Communities, "to reduce the avoidable input and body burden".

#### C.4 Statistical uncertainty of the test procedure and interpretation of results (see 4.2)

Most chemical test methods are designed to measure the total amount of a substance in a material. This makes it easier to obtain an accurate result with close statistical agreement between laboratories because there is an absolute or true value.

<sup>2)</sup> See Council Directive 88/378/EEC of 3 May 1988 concerning the safety of toys (published in the EU Official Journal of 16 July 1988, No. L 187).

Because of the way bioavailability is defined in the Toy Safety Directive, the test methods described in this standard permit the amount of soluble element migration from a toy material to be measured. With this type of chemical test the result depends on the specified conditions of test and there is no absolute or true value. Consequently, it is more difficult to obtain close statistical agreement between laboratories when performing such migration tests.

This is illustrated by the statistical information in the 1988 edition of the standard taken from a 1987 European interlaboratory test involving 17 laboratories. Results on an identical material varied by at least 30 % and up to 50 % between laboratories depending on the instrumental technique used to measure the soluble element concentration of the filtrate. Moreover, these figures would be about three times higher if adjusted to give a 95 % confidence level.

This degree of statistical uncertainty creates problems for manufacturers and authorities if test results are near the maximum limits allowed in the standard. Then it is not statistically possible for a toy to pass or fail and it leads to inconsistency in the interpretation of results.

There is no direct relationship between the total element content of a toy material and the soluble migration of that element under the standard test conditions. Therefore, measuring the total element content and converting the result to give a soluble element figure is not an answer to this problem. Setting maximum total element limits is a possibility but requires an amendment to the Toy Safety Directive (cf. C.1).

Since 1988, the test procedure for paint coatings on toys has been thoroughly investigated to find which parameters significantly effect the results. The most critical parameter is the shape, size and mass of the paint particles produced by removal of the paint and its subsequent comminution. Other less critical parameters include the method of shaking, the temperature, and the type and porosity of filter paper.

As a result, a defined scraping and comminution procedure for collecting a 300 µm to 500 µm paint test portion was proposed as a revision to the test procedure. A European interlaboratory test was conducted in 1993 with 29 laboratories participating to compare the amended procedure with that in the 1988 standard.

The test showed that results on an identical material can vary by at least 25 % and up to 80 % depending on the instrumental technique used to measure the soluble elements concentration of the filtrate.

Statistical agreement between laboratories showed improvement using a defined scraping procedure, but not when collecting a 300 µm to 500 µm test portion. However, any improvement was not significant enough to justify the proposed changes.

The trial confirmed that different instrumental techniques contribute to the statistical uncertainty of the test procedure. It was also noted that laboratories need to check and calibrate their instruments on a regular basis to ensure accurate readings. Inductively Coupled Plasma (ICP) analysis was more widely used by laboratories this time and tended to show better agreement for most of the elements, particularly arsenic, antimony and selenium. However, it is not as sensitive as hydride generation methods for low levels of the same elements.

A test procedure that produces results varying, at best, by 25 % between laboratories would normally be considered as technically unsuitable as a reference method. However, in reality, toys will either easily pass or fail this test and only in relatively few cases will a result come within the area of uncertainty. When this occurs, it is important that laboratories interpret the results in the same way.

It has been accepted that the test procedure cannot be improved without imposing time consuming, costly, and in some cases, impractical burdens on laboratories with little benefit in terms of statistical agreement and safety. Therefore, the procedure allows laboratories to use their preferred technique for scraping the paint off the toys, collecting the portion that passes through a 500 µm sieve and determining the soluble elements concentration of the filtrate.

To achieve consistent interpretation of results, a correction factor for each element has been introduced into the standard applicable to all instrumental techniques. These are taken from the precision data in the 1988 standard and are used when an analytical result equals or exceeds the maximum limit. The analytical result is adjusted as described in 4.2, using the relevant correction factor. This way of interpreting the results is perfectly adequate as a screening test to differentiate between safe and unsafe toys as well as ensuring the safety of children.

In future, it is recommended that laboratories check and compare their performances when using the test procedure by using reference materials and participating in a proficiency scheme.

## **C.5 Reagents** (see 6.1)

## **C.6 Apparatus** (see 6.2)

### **C.6.1 Plain weave stainless steel wire cloth sieve** (see 6.2.1)

See C.4.

### **C.6.2 C-Device for measuring pH** (see 6.2.2)

The measurement of pH is now not restricted to the use of a pH meter.

### **C.6.3 Centrifuge (see 6.2.4)**

This is a new subclause and specifies the performance requirements for centrifuging limits and amount of time permitted for centrifuging (to ten minutes) and requires this to be reported under item 10 e). The latter is necessary as centrifuging has been reported to increase the extraction of barium.

### **C.6.4 Selection of containers (6.2.6)**

The indication of the gross volume of the containers is intended to ensure adequate movement of the solution leading to a more efficient extraction.

## **C.7 Selection of test portions (see 7)**

The practice of analyzing 'composite' (combination of different materials or colours) test portions is neither appropriate nor will it normally be necessary (with the availability of the '5,0 ml' test method). The analysis of composite materials is not satisfactory because from a theoretical viewpoint it can result in a reduction in the migration of toxic elements that would otherwise occur. A simple example is known to have occurred, i.e. barium extraction from paint was reduced when co-extracted with another paint. This may have been the result of a counter-ion in the second paint which would cause the barium to be precipitated. Sulfate is such a counter-ion; whether sulfate itself was involved is not known and is not important for the establishment of this principle. Thus, except for the cases where the separation of colours or toy material is impractical (e.g. dot printing), each discrete area is treated as a single sample.

The note makes it possible to test toy materials which are not in the form of a toy for reference purposes. However, the standard clearly requires taking of test portions from the toy itself.

## **C.8 Paper and board (see 8.3)**

### **C.8.1 Sample removal/preparation procedure (see 8.3.1)**

Paper and board are to be treated as if they were a single material, i.e. surface coatings, if present, are not to be removed, but test portions will include representative parts of the surface. This procedure has been adopted because in the practical situation of a child chewing paper and board, preferential removal of a coating is unlikely and the substrate is equally important.

## **C.9 Textiles, whether natural or synthetic (see 8.4)**

### **C.9.1 Sample removal/preparation procedure (see 8.4.1)**

It is not feasible to take separate coloured test portions from a complex patterned fabric. It is therefore required that a single test portion be taken that represents all the colours in the material.

## **C.10 Glass/ceramic/metallic materials (see 8.5)**

### **C.10.1 Sample removal/preparation procedure (see 8.5.1)**

Toys or components which do not fit entirely within the 'small parts cylinder' specified in EN 71-1 are not tested because there is no hazard from ingestion and no significant extraction occurs with saliva simulator. The small parts cylinder is used to assess the size of the toy or toy components for all relevant age groups. Comminution of glass, ceramic and metallic materials is inappropriate. Agitation of the test solution would be impractical for many examples and thus extraction is carried out without shaking. The diameter of the vessel and the orientation of the test portion have been selected to minimize variables.

Glass, ceramic and metallic materials completely coated so that no glass, ceramic or metal is accessible as defined in EN 71-1 are not tested according to this requirement.

Where glass, ceramic and metal surfaces are accessible even when partially covered by a coating, these are tested in accordance with 8.5.2 after removal of the partial coating entirely in accordance with the method as described in 8.1.1. This procedure is a compromise as only a single toy may be taken as a sample as specified in clause 7 of this standard.

## **C.11 Other materials, whether mass coloured or not (see 8.6)**

This subclause covers mass coloured materials and other materials which are not coloured such as wood, hardboard, leather and bone, etc. which may have received some other treatment, but were not covered by the 1988 standard.

## Annex ZA (informative)

### Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

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 EU Directive 88/378/EEC.

**Warning.** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clause of this standard as detailed in table ZA.1 is likely to support requirements of Directive 88/378/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the directive concerned and associated EFTA regulations.

**Table ZA.1 – Correspondence between this European Standard and EU Directives**

Essential requirements of Directive 88/378/EEC as given in its Annex II	Corresponding clauses of this standard
II.31., 2. and 3. (Chemical properties)	6.1.6, 8.7.1, 8.7.2, 8.8.1, 8.9.1, 8.9.2