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Safety of toys —

Part 3:
Migration of certain elements

Sécurité des jouets —

Partie 3: Migration de certains éléments

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8124-3 was prepared by Technical Committee ISO/TC 181, *Safety of toys*.

This second edition cancels and replaces the first edition (ISO 8124-3:1997) which has been technically revised.

ISO 8124 consists of the following parts, under the general title *Safety of toys.*

- *Part 1: Safety aspects related to mechanical and physical properties*
- *Part 2: Flammability*
- *Part 3: Migration of certain elements*
- *Part 4: Swings, slides and similar activity toys for indoor and outdoor family domestic use*

Introduction

The requirements of this part of ISO 8124 are based on the bioavailability of certain elements resulting from the use of toys and should not, as an objective, exceed the following 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 values, 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 of the various toy materials has been gauged at the currently accepted value of 8 mg/d, being aware that in certain individual cases these values might be exceeded.

By combining the daily intake with the bioavailability values listed above, limits are obtained for various toxic elements in micrograms per gram of toy material (milligrams per kilogram) and are detailed in Table 1. The values obtained have been adjusted to minimize children's exposure to toxic elements in toys and to ensure analytical feasibility, taking into account limits achievable under current manufacturing conditions (see Annex C).

Safety of toys —

Part 3:
Migration of certain elements

1 Scope

1.1 This part of ISO 8124 specifies maximum acceptable levels and methods of sampling and extraction prior to analysis for the migration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and from parts of toys.

1.2 Maximum acceptable levels are specified for the migration of the elements listed in 1.1 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 and non-woven textiles (see 8.2);
- paper and paperboard, up to a maximum mass per unit area of 400 g/m^2 (see 8.3);
- natural, artificial or synthetic textiles (see 8.4);
- glass/ceramic/metallic materials, excepting lead solder when used for electrical connections (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 to be used as such in the toy, including finger paints, varnishes, lacquers, glazing powders and similar materials in solid or liquid form (see 8.9).

1.3 The requirements in this part of ISO 8124 apply to the following toys and toy components of toys and toy materials (see C.2.1):

- all intended food and oral contact toys, cosmetic toys and writing instruments categorized as toys, irrespective of any age grading or recommended age labelling;
- all toys intended for or suitable for children up to 72 months of age;
- accessible coatings, irrespective of any age grading or recommended age labelling;
- accessible liquids, pastes, gels (e.g. liquid paints, modelling compounds), irrespective of any age grading or recommended age labelling.

1.4 Packaging materials are not included, unless they are intended to be kept, e.g. boxes, containers, or unless they form part of the toy or have intended play value (see C.2.2).

NOTE No requirements are given for toys and parts of toys which, due to their accessibility, function, mass, size or other characteristics, are obviously unlikely to be sucked, licked or swallowed, bearing in mind the normal and foreseeable behaviour of children (e.g. the coating on the crossbeam of a swing set, the tyres of a toy bicycle).

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 8124-1, *Safety of toys — Part 1: Safety aspects related to mechanical and physical properties*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

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
all layers of material formed or deposited on the base material of a 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 result obtained in the blank test using that method by the laboratory carrying out the analysis

3.4
mass-coloured materials
materials, such as wood, fibreboard, hardboard, leather, bone and other porous substances, which have absorbed colouring matter without formation of a coating

3.5
paper and paperboard
that having a maximum mass per unit area of 400 g/m^2

NOTE Above this mass per unit area, the substance is treated as "other material", and may be fibreboard or hardboard, etc.

3.6
scraping
mechanical process for removal of coatings down to the base material

3.7
toy material
all accessible materials present in a toy

4 Maximum acceptable levels

4.1 Specific requirements

See C.3.

Toys and parts of toys, as specified in Clause 1, are deemed to meet the requirements of this part of ISO 8124 when the adjusted value of migration of elements from them comply with the maximum limits given in Table 1 when tested in accordance with Clauses 7, 8 and 9.

4.2 Interpretation of results

See C.4.

Due to the precision of the methods specified in this part of ISO 8124, an adjusted analytical result is required to take into consideration the results of interlaboratory trials. The analytical results obtained in accordance with 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 part of ISO 8124 if the adjusted analytical result for the migrated element is less than or equal to the value given in Table 1.

Table 1 — Maximum acceptable element migration from toy materials

Values in milligrams per kilogram of toy material

Toy material	Element							
	Sb	**As**	**Ba**	**Cd**	**Cr**	**Pb**	**Hg**	**Se**
Any toy material given in Clause 1, except modelling clay and finger paint	60	25	1 000	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 (%)	60	60	30	30	30	30	50	60

EXAMPLE

An analytical result for lead of 120 mg/kg was obtained. The necessary analytical correction taken from Table 2 is 30 %. Therefore, the adjusted analytical result is

$$120-\frac{120\times 30}{100}=120-36$$

$$= 84 \text{ mg/kg.}$$

This is deemed as complying with the requirements of this part of ISO 8124 (maximum acceptable migration of lead as given in Table 1 is 90 mg/kg).

5 Principle

Soluble elements are extracted from toy materials under conditions that simulate the material remaining in contact with stomach acid for a period of time after swallowing. The concentrations of the soluble elements are then determined quantitatively by specified analytical methods with specified detection limits.

6 Reagents and apparatus

NOTE No recommendation is made for the reagents, materials and apparatus necessary for carrying out elemental analyses within the detection limits specified in Clause 9.

6.1 Reagents

During the analyses, use only reagents of recognised analytical grade.

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

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

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

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

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

6.1.6 General purpose reagent *n*-heptane, (C_7H_{16}); 99 %.

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

6.2 Apparatus

See C.5.

Normal laboratory apparatus and

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

6.2.2 Means of measuring pH to an accuracy of ± 0,2 pH units. Cross-contamination shall be prevented.

See C.5.2.

6.2.3 Membrane filter, of pore size 0,45 µm.

6.2.4 Centrifuge, capable of centrifuging at $(5\,000 \pm 500)\ g$[1].

See C.5.3.

6.2.5 Means of agitating the mixture, at a temperature of (37 ± 2) °C.

6.2.6 Series of containers, of gross volume between 1,6 × and 5,0 × that of the volume of hydrochloric acid extractant.

See C.5.4.

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1) $g = 9{,}806\ 65\ \text{m/s}^2$.

7 Selection of test portions

See C.6.

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 the accessible parts (see ISO 8124-1) of a 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. Test portions may be composed of more than one material or colour only if physical separation, e.g. dot printing, patterned textiles or mass limitation reasons, precludes the formation of discrete specimens.

NOTE The requirement does not preclude the taking of reference portions from toy materials in a different form, provided that they are representative of the relevant material specified above and the substrate upon which they are deposited.

Test portions of less than 10 mg of material shall not be tested.

8 Preparation and extraction of test portions

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

8.1.1 Test portion preparation

Remove the coating from the laboratory sample by scraping (see 3.6) at room temperature and comminute it at a temperature not exceeding ambient. Collect enough coating to obtain a test portion of preferably not less than 100 mg which will pass through a metal sieve of aperture 0,5 mm (6.2.1).

If only between 10 mg and 100 mg of comminuted uniform coating is available, extract this in accordance with 8.1.2 and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used. Report the mass of the test portion in accordance with 10 e).

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

8.1.2 Extraction procedure

Using a container of appropriate size (6.2.6), mix the test portion prepared in 8.1.1 with 50 × its mass of an aqueous HCl solution at (37 ± 2) °C of $c(\text{HCl})$ 0,07 mol/l (6.1.1). [Where the test portion has only a mass of between 10 mg and 100 mg, mix the test portion with 5,0 ml of this solution (6.1.1) at (37 ± 2) °C.]

Shake for 1 min. Check the acidity of the mixture (6.2.2). 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 (6.1.4) until the pH of the mixture is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C.

Without delay, efficiently separate the solids from the solution, firstly by filtration using a membrane filter (6.2.3) and, if necessary, by centrifuging at up to 5 000 g (6.2.4). Carry out the separation as rapidly as possible after completion of the standing time. If centrifuging is used, it shall take no longer than 10 min and shall be reported in accordance with 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by adding hydrochloric acid so that the concentration of the stored solution is approximately $c(\text{HCl}) = 1$ mol/l (6.1.3). Report such stabilization in accordance with 10 e).

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

8.2.1 Test portion preparation

Obtain a test portion of preferably not less than 100 mg of the polymeric or similar materials, while avoiding heating of the materials, according to the following procedure.

Cut out test portions from those 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 piece shall, in the uncompressed condition, have no dimension greater than 6 mm.

If the laboratory sample is not of a uniform material, obtain a test portion from each different material present in a mass of 10 mg or more. Where there is only between 10 mg and 100 mg of uniform material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

8.2.2 Extraction procedure

Follow the extraction procedure in 8.1.2 using the test portions prepared in accordance with 8.2.1.

8.3 Paper and paperboard

8.3.1 Test portion preparation

See C.7.

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

If the laboratory sample is not of a uniform material, where possible, obtain a test portion from each different material present in a mass of not less than 100 mg. Where there is only between 10 mg and 100 mg of uniform material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

If the paper or paperboard to be tested is coated with paint, varnish, lacquer, printing ink, adhesive or similar coating, test portions of the coating shall not be taken separately. In such cases, take test portions from the material so that they also include representative parts of the coated area and report this in accordance with 10 e). Extract test portions obtained in accordance with 8.3.2.

8.3.2 Extraction procedure

Macerate the test portion prepared in 8.3.1 with 25 × its mass of water (6.1.7) at (37 ± 2) °C so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to the appropriate-sized container (6.2.6). Add to the mixture a mass of aqueous solution of $c(\text{HCl}) = 0{,}14$ mol/l (6.1.2) at (37 ± 2) °C which has 25 × the mass of the test portion.

Shake for 1 min. Check the acidity of the mixture (6.2.2). 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 (6.1.4) until the pH of the mixture is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C.

Without delay, efficiently separate the solids from the solution, firstly by filtration using a membrane filter (6.2.3) and, if necessary, by centrifuging at up to 5 000 g (6.2.4). Carry out the separation as rapidly as possible after completion of the standing time. If centrifuging is used, it shall take no longer than 10 min and shall be reported in accordance with 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by adding hydrochloric acid so that the concentration of the stored solution is approximately $c(\text{HCl}) = 1$ mol/l. Report such stabilization in accordance with 10 e).

8.4 Natural, artificial or synthetic textiles

8.4.1 Test portion preparation

See C.8.

Obtain a test portion of preferably not less than 100 mg by cutting the textile material into pieces that in the uncompressed condition have no dimension greater than 6 mm.

If the sample is not of a uniform material or colour, where possible, obtain a test portion from each different material or colour present in a mass greater than 100 mg. Materials or colours present in amounts 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.

8.4.2 Extraction procedure

Follow the extraction procedure in 8.1.2 using the test portions prepared in accordance with 8.4.1.

8.5 Glass/ceramic/metallic materials

8.5.1 Test portion preparation

See C.9.

Toys and toy components shall first be subjected to the small parts test in accordance with ISO 8124-1. If the toy or component fits entirely within the small parts cylinder and contains accessible glass, ceramic or metallic materials (excepting lead solder when used for electrical connections), then the toy or component shall be extracted in accordance with 8.5.2 after removal of any coating in accordance with 8.1.1.

NOTE Toys and toy components that have no accessible glass, ceramic or metallic materials do not require extraction in accordance with 8.5.2.

8.5.2 Extraction procedure

Place the weighed toy or toy component in a 50 ml glass cylinder with a nominal height of 60 mm and diameter of 40 mm.

NOTE This type of container will take all components/toys that fit inside the small parts cylinder defined in ISO 8124-1.

Add a sufficient measured volume of an aqueous solution of $c(\text{HCl}) = 0{,}07$ mol/l (6.1.1) at (37 ± 2) °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 ± 2) °C.

Without delay, efficiently separate the solids from the solution, firstly by decantation followed by filtration using a membrane filter (6.2.3) and, if necessary, by centrifuging at up to 5 000 g (6.2.4). Carry out the separation as rapidly as possible after completion of the standing time. If centrifuging is used, it shall take no longer than 10 min and shall be reported in accordance with 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by adding hydrochloric acid so that the concentration of the stored solution is approximately $c(\text{HCl}) = 1$ mol/l (6.1.3). Report such stabilization in accordance with 10 e).

8.6 Other materials, whether mass-coloured or not, e.g. wood, fibreboard, bone and leather

See C.10.

8.6.1 Test portion preparation

Obtain a test portion of preferably not less than 100 mg of the material in accordance with 8.2.1, 8.3.1, 8.4.1 or 8.5.1, as appropriate.

If the laboratory sample is not of uniform material, a test portion shall be obtained from each different material present in a mass of 10 mg or more. Where there is only between 10 mg and 100 mg of uniform material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

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

8.6.2 Extraction procedures

Extract the materials in accordance with 8.1.2, 8.3.2 or 8.5.2, as appropriate. Report the method used in accordance with 10 e).

8.7 Materials intended to leave a trace

8.7.1 Test portion preparation for materials in solid form

Obtain a test portion of preferably not less than 100 mg by cutting the material into pieces which in the uncompressed condition have no dimension 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 of 10 mg or more. Where there is only between 10 mg and 100 mg of material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

If the material contains any grease, oil, wax or similar material, enclose the test portion in hardened filter paper and remove these ingredients with *n*-heptane (6.1.6) by extraction before treatment of the test portion as described in 8.7.4. Take analytical measures to ensure that the removal of the ingredients referred to is quantitative. Report the solvent used in accordance with 10 e).

8.7.2 Test portion preparation for materials in liquid form

Obtain a test portion of preferably not less than 100 mg of the material from the laboratory sample. The use of an appropriate solvent to facilitate the obtaining of 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 at a mass of 10 mg or more. Where there is only between 10 mg and 100 mg of material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

If the material is intended to solidify in normal use and contains grease, oil, wax or similar material, allow the test portion to solidify under normal-use conditions and enclose the resulting material in hardened filter paper. Remove the grease, oil, wax or similar material using *n*-heptane (6.1.6) by extraction before treatment of the test portion as described in 8.7.4. Take analytical measures to ensure that the removal of the ingredients referred to is quantitative. Report the solvent used in accordance with 10 e).

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

Using a container of appropriate size (6.2.6), mix the test portion prepared in accordance with 8.7.1 or 8.7.2 with 50 × its mass of an aqueous HCl solution at (37 ± 2) °C of c(HCl) = 0,07 mol/l (6.1.1). For a test portion of mass between 10 mg and 100 mg, mix the test portion with 5,0 ml of this solution at (37 ± 2) °C.

Shake for 1 min. Check the acidity of the mixture (6.2.2). 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 using hydrochloric acid [c(HCl) approximately 6 mol/l (6.1.5)] in order to avoid overdilution. Report in accordance with 10 e) the amount of hydrochloric acid used to adjust the pH in relation to the total amount of solution.

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of c(HCl) approximately 2 mol/l (6.1.4) until the pH is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C prior to elemental analysis.

8.7.4 Extraction procedure for samples containing grease, oil, wax or similar materials

With the test portion as prepared in 8.7.1 or 8.7.2 remaining in the hardened filter paper, macerate the test portion with water (6.1.7) which has 25 × the mass of the original material, at (37 ± 2) °C, so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to a container of appropriate size (6.2.6). Add to the mixture a mass of aqueous solution of c(HCl) = 0,14 mol/l (6.1.2) at (37 ± 2) °C which has 25 × the mass of the original test portion.

In the case of a test portion of original mass between 10 mg and 100 mg, macerate the test portion with 2,5 ml of water (6.1.7). Quantitatively transfer the mixture to the appropriate-sized container (6.2.6). Add 2,5 ml aqueous solution of c(HCl) = 0,14 mol/l (6.1.2) at (37 ± 2) °C to the mixture.

Shake for 1 min. Check the acidity of the mixture (6.2.2). 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 using hydrochloric acid of c(HCl) approximately 6 mol/l (6.1.5) in order to avoid overdilution. Report in accordance with 10 e) the amount of hydrochloric acid used to adjust the pH in relation to the total amount of solution.

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of c(HCl) approximately 2 mol/l (6.1.4) until the pH is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C.

NOTE The volume of HCl solution of c(HCl) = 0,07 mol/l (see 8.7.3) or c(HCl) = 0,14 mol/l, as the case may be, is 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 (6.2.3) and, if necessary, by centrifuging at up to 5 000 g (6.2.4). Carry out the separation as rapidly as possible after completion of the standing time. If centrifuging is used, it shall take no longer than 10 min and shall be reported in accordance with 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by the addition of hydrochloric acid so that the concentration of the stored solution is approximately c(HCl) = 1 mol/l. Report such stabilization in accordance with 10 e).

8.8 Pliable modelling materials, including modelling clays and gels

8.8.1 Test portion preparation

Obtain a test portion of not less than 100 mg of the material from the laboratory sample; obtain a test portion from each different material in the laboratory sample.

If the material contains grease, oil, wax or similar material, enclose the test portion in hardened filter paper and remove these ingredients using *n*-heptane (6.1.6) by extraction before treatment of the test portion as described in 8.8.3. Take analytical measures to ensure that the removal of the ingredients referred to is quantitative. Report the solvent used in accordance with 10 e).

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

Using a container of appropriate size (6.2.6), mix the test portion prepared in accordance with 8.8.1, after breaking up of clay or doughy materials, if appropriate, with 50 × its mass of an aqueous solution at (37 ± 2) °C of $c(\text{HCl}) = 0{,}07$ mol/l (6.1.1).

Shake the mixture for 1 min. 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 using hydrochloric acid of $c(\text{HCl})$ approximately 6 mol/l (6.1.5) in order to avoid overdilution. Report in accordance with 10 e) the amount of hydrochloric acid used in relation to the total amount of solution.

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of $c(\text{HCl})$ approximately 2,0 mol/l (6.1.4) until the pH is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C.

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

With the test portion as prepared in 8.8.1 remaining in the hardened filter paper, macerate the test portion with of water (6.1.7) which has 25 × the mass of the original material, at (37 ± 2) °C, so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to a container of appropriate size (6.2.6). Add to the mixture a mass of aqueous solution of $c(\text{HCl}) = 0{,}14$ mol/l (6.1.2) at (37 ± 2) °C which has 25 × the mass of the original test portion.

Shake for 1 min. Check the acidity of the mixture (6.2.2). 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 using an aqueous solution of $c(\text{HCl})$ approximately 6 mol/l (6.1.5) in order to avoid overdilution. Report in accordance with 10 e) the amount of hydrochloric acid used in relation to the total amount of solution.

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of $c(\text{HCl})$ approximately 2,0 mol/l (6.1.4) until the pH is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C.

NOTE The volume of the HCl solution of $c(\text{HCl}) = 0{,}07$ mol/l (see 8.8.2) or $c(\text{HCl}) = 0{,}14$ mol/l, as the case may be, is 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 (6.2.3) and, if necessary, by centrifuging at up to 5 000 g (6.2.4). Carry out the separation as rapidly as possible after completion of the standing time. If centrifuging is used, it shall take no longer than 10 min and shall be reported in accordance with 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by adding hydrochloric acid so that the concentration of the stored solution is approximately $c(\text{HCl}) = 1$ mol/l. Report such stabilization in accordance with 10 e).

8.9 Paints, including finger paints, varnishes, lacquers, glazing powders and similar materials in solid or liquid form

8.9.1 Test portion preparation for materials in solid form

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

A test portion shall be obtained from each different material present in the laboratory sample at a mass of 10 mg or more. Where there is only between 10 mg and 100 mg of material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

If the material contains any grease, oil, wax or similar material, enclose the test portion in hardened filter paper and remove these ingredients using *n*-heptane (6.1.6) by extraction before treatment of the test portion as described in 8.9.4. Take analytical measures to ensure that the removal of the ingredients referred to is quantitative. Report the solvent used in accordance with 10 e).

If the test portion is removed by scraping, comminute it so that the material will pass through a metal sieve with an aperture of 0,5 mm (6.2.1).

8.9.2 Test portion preparation for materials in liquid form

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

A test portion shall be obtained from each different material present in the laboratory sample and forming a mass of 10 mg or more. Where there is only between 10 mg and 100 mg of material, report the mass of the test portion in accordance with 10 e) and calculate the quantity of the appropriate elements as if a test portion of 100 mg had been used.

If the material is intended to solidify in normal use and contains grease, oil, wax or similar material, allow the test portion to solidify under normal-use conditions and enclose the resulting material in hardened filter paper. Remove the grease, oil, wax or similar material using *n*-heptane (6.1.6) by extraction before treatment of the test portion as described in 8.9.4. Take analytical measures to ensure that the removal of the ingredients referred to is quantitative. Report the solvent used in accordance with 10 e).

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

Follow the extraction procedure in 8.7.3 using the test portions prepared in accordance with 8.9.1 or 8.9.2.

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

With the test portion as prepared in 8.9.1 or 8.9.2 remaining in the filter paper, macerate the test portion with water (6.1.7) which has 25 × the mass of the original material, at (37 ± 2) °C, so that the resulting mixture is homogeneous. Quantitatively transfer the mixture to a container of appropriate size (6.2.6). Add to the mixture a mass of aqueous solution of $c(\text{HCl}) = 0{,}14$ mol/l (6.1.2) at (37 ± 2) °C which has 25 × the mass of the original test portion.

Shake for 1 min. 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 using an aqueous solution of $c(\text{HCl})$ approximately 6 mol/l (6.1.5) in order to avoid overdilution. Report in accordance with 10 e) the amount of hydrochloric acid used in relation to the total amount of solution.

If only a small quantity of alkaline material is present and the pH of the mixture is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of $c(\text{HCl})$ approximately 2 mol/l (6.1.4) until the pH is between 1,0 and 1,5.

Protect the mixture from light. Agitate the mixture continuously at (37 ± 2) °C (6.2.5) for 1 h and then allow to stand for 1 h at (37 ± 2) °C.

NOTE The volume of the solution of $c(\text{HCl}) = 0{,}07$ mol/l (see 8.7.3) or $c(\text{HCl}) = 0{,}14$ mol/l, as the case may be, is 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 (6.2.3) and, if necessary, by centrifuging at up to 5 000 g (6.2.4). Carry out the separation as rapidly as possible after completion of the standing time. If centrifuging is used, it shall take no longer than 10 min and shall be reported in accordance with 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by adding hydrochloric acid so that the concentration of the stored solution is approximately $c(\text{HCl}) = 1$ mol/l. Report such stabilization in accordance with 10 e).

9 Detection limits of quantitative elemental analysis

The detection limit (of the analytical 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.

For the quantitative analysis of the extracts of toys for the migrated elements listed in Clause 1, methods having a detection limit of a maximum of 1/10 of the values to be determined (see 4.1 and Table 1) shall be considered adequate.

Methods with detection limits other than that specified above may be used if the uncertainty of the measurement is considered when determining compliance or non-compliance to the specified limit. Laboratories using methods deviating from this requirement shall report the detection limit under 10 c).

10 Test report

The test report shall contain at least the following information:

a) type and identity of the product and/or material tested;

b) a reference to this part of ISO 8124; i.e. ISO 8124-3:2010;

c) the technique used for determining the quantity of each migrated element, and the detection limit if different from the requirements in Clause 9;

d) the adjusted results (see 4.2) of the quantitative elemental analysis, expressed as milligrams migrated element per kilogram of toy material, stating that the result is related to the element in the solution;

e) details of the procedure used (from Clause 8) to prepare the test portion (including, for example, if base material was incorporated, if centrifugation was required to separate the solids from the solution prior to analysis, if additional acid was required to lower the pH, if the ratio of solid to acid extractant exceeds 1:50 and the solvent used for removing any grease, oil, wax or similar ingredient in toy materials) and if the solution was adjusted to 1mol/l for overnight storage;

f) any departure, by agreement or otherwise, from the preparation and extraction procedures specified;

g) date of the test.

Annex A
(normative)

Sieve requirements

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 shall exceed the nominal aperture size plus this number)
0,500	0,315	+ 0,090	± 0,018	+ 0,054

Annex B
(informative)

Selection of procedure

Table B.1 is a guideline for the choice of procedure to be used for the various toy materials.

Table B.1 — Guidelines for choosing the procedure for preparation and extraction of test portions

Toy material	Relevant subclause
Paper or paperboard	8.3
Plastic-coated paper or paperboard	8.2
Removable coating	8.1 If accessible, test base material in accordance with 8.2, 8.4, 8.5 and 8.6
Non-textile polymer	8.2
Textile	8.4
Glass/ceramic/metallic	8.5
Other material	8.6
Material intended to leave a trace	8.7
Pliable modelling material or gel	8.8
Paint, varnish, lacquer, glazing powder or similar material in solid or liquid form	8.9

Annex C
(informative)

Background and rationale

C.1 Introduction

The approach adopted in this part of ISO 8124 is based on the principle of bioavailability as defined in the European Directive 88/378/EEC of May 1988[2] concerning the safety of toys. This has led to addressing the migration of soluble toxic elements from toy materials. The bioavailability figures quoted in the Introduction may be combined with an assumed daily intake of 8 mg/d of toy material in order to derive maximum permissible levels in mg/kg of the element in a particular toy material. Exact correlation of maximum limits with bioavailability as in the case of barium (see C.3) does not always occur, as some adjustments were made in EN 71-3[1] in order to take account of scientific and political advice on levels that provide an acceptable or avoidable body burden.

The approach specifying total element determinations was discarded for several reasons, including the following.

a) The EU Directive specifies limits for bioavailability. To date, no relationship has been established between the total element content of toy materials with a bioavailability.

b) Some compounds, such as barium sulfate, can be included in some products at a relatively high level to render them radio-opaque. Further requirements would be necessary to allow for this use of barium which does not necessarily contribute to the bioavailable levels.

c) Cadmium compounds can be used as stabilizers in plastics such as polyvinylchloride (PVC). Once again, the bioavailability of cadmium used for this purpose is not related to the total amount of the element present. A case can be made for selenium, which can be present as a constituent of insoluble pigments, etc. (See also C.4.)

C.2 Scope

C.2.1 Requirement

See 1.3.

Subclause 1.3 is intended to indicate an approach to the decision of what toys, or toy components, are excluded from this part of ISO 8124 because of characteristics that render them unlikely to present a risk of harm from the absorption of toxic elements after ingestion of materials that may contain toxic elements.

This part of ISO 8124 does not specify requirements for inaccessible materials (see ISO 8124-1) from which the migration of toxic elements is not possible or likely during normal or foreseeable use.

In addition, no requirements are given for toys and parts of toys which, due to their accessibility, function, mass, size or other characteristics, are obviously unlikely to be sucked, licked or swallowed, bearing in mind the normal and foreseeable behaviour of children (e.g. the coating on the crossbeam of a swing set, the tyres of a toy bicycle).

This was considered a logical approach for a number of reasons, including the following.

- Three separate observational studies on the mouthing behaviour of children (see References [4], [5], [6]) indicate that mouthing behaviour primarily occurs in children under 18 months and decreases significantly thereafter as children age. A fourth study, in which the mouthing behaviour of children up to eight years old was observed, confirmed that mouthing is insignificant in older children. See Reference [7]. This is consistent with patterns of child development, which show a peak period for mouthing activity while children are teething, reducing as children become more mobile. Toys intended for children over the age of six years were therefore considered not to pose a significant risk of injury through the ingestion of toxic elements. However, irrespective of any age grading or recommended age labelling, accessible coatings are considered a special case since they might be removed during play and possibly be ingested either directly or via the hands and fingers.

- The larger the toy or the less accessible the material, the lower the risk of ingestion of components containing toxic elements.

- It is considered that all toys that might be placed in the mouth or close to the mouth (e.g. pretend/toy food, pencils marketed as toys or parts of toys) should comply with toxic element requirements, irrespective of any age grading or recommended age labelling.

- It is considered that toys that are capable of easy ingestion in significant quantities (e.g. liquid paints, modelling compounds, gels) should comply with toxic element requirements, irrespective of any age grading or recommended age labelling.

C.2.2 Packaging

See 1.4.

The wording “unless they form part of the toy” in 1.4 is intended to mean, for example, boxes containing jigsaw puzzles or packaging on which the instructions are included in the case of games, etc., but taking into account the second listed item of 1.3 restricting the requirements to toys intended for children up to 72 months of age. It is not intended to address, for example, blister packs containing simple instructions.

C.3 Specific requirements

See 4.1.

The maximum acceptable level 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 acidic extraction solution [c(HCl) = (0,07 ± 0,005) 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, due to the statistical uncertainty of the determination, a PASS or FAIL could not be indicated.

- The formation of non-bioavailable colloidal barium sulfate crystals in the filtrate resulted in levels of apparently soluble barium which exceeded 500 mg/kg because of problems with filtration.

- In addition, the previous maximum level of migration of barium of 500 mg/kg from toy materials was not consistent with 25,0 µg/d bioavailability and the 8 mg/d of toy material intake; 25,0 µg correspond 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 value. 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 25,0 µg value has been reduced from an initial value of 50,0 µg, not for toxicological reasons, but, according to the Commission of the European Communities, “to reduce the avoidable input on body burden”.