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Safety of toys —

Part 3:
Migration of certain elements

Sécurité des jouets —

Partie 3: Migration de certains éléments

Reference number
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Foreword

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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.

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

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

— *Part 1: Mechanical and physical properties*

— *Part 2: Flammability*

— *Part 3: Migration of certain elements*

Annexes A and B form an integral part of this part of ISO 8124. Annexes C, D and E are for information only.

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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:

— 1,4 µg for antimony[1];
— 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.

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 D).

1) This level differs from the level of 0,2 µg given in EN 71-3:1994.

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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, except materials not accessible (see ISO 8124-1).

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 (see 8.2);

— paper and paper board, up to a maximum mass per unit area of 400 g/m^2 (see 8.3);

— natural 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 For the purposes of this part of ISO 8124, the following criteria are considered appropriate in the categorization of toys which can be sucked, licked or swallowed:

— 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 where there is a probability that those parts or components may come into contact with the mouth (see annex D).

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 ISO 8124.

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8124. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8124 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8124-1:— [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 part of ISO 8124 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 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.

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

3.5 scraping: Mechanical process for removal of coatings down to the base material.

3.6 toy material: All accessible materials present in a toy.

4 Maximum acceptable levels

4.1 Specific requirements

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 (see annex D).

4.2 Interpretation of results

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.

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1) To be published.

Table 1 — Maximum acceptable element migration from toy materials

Values in milligrams per kilogram 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 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 which 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 unspecified 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 recognized analytical grade (see annex D).

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

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

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

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

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

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

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

6.2 Apparatus

Normal laboratory apparatus and

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

6.2.2 Means of measuring pH with an accuracy of ± 0,2 pH units. Cross-contamination shall be prevented (see annex D).

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

6.2.4 Centrifuge, capable of centrifuging at (5 000 ± 500)g[1] (see annex D).

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

6.2.6 Series of containers, of gross volume between 1,6 times and 5,0 times that of the volume of hydrochloric acid extractant (see annex D).

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 ISO 8124-1) of a single toy sample. When appropriate, the toy shall be subjected to relevant tests in accordance with ISO 8124-1, before the accessibility is considered. 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. (See annex D.)

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. (See annex D.)

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

1) g = 9,806 65 m/s^2

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 (3.5) 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 under 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 times its mass of an aqueous HCl solution at (37 ± 2) °C of c(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. If the pH 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 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 000g (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 under 10 e).

If the resulting solutions are to be stored for more than one working day prior to elemental analysis, stabilize them by addition of hydrochloric acid so that the concentration of the stored solution is approximately c(HCl) = 1 mol/l. Report such stabilization under 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, whilst 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 greater than 10 mg. Where there is only between 10 mg and 100 mg of uniform material, report the mass of the test portion under 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 paper board

8.3.1 Test portion preparation (see annex D)

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

If the laboratory sample is not of a uniform material, 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 under 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 paper board 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 under 10 e). Extract test portions so obtained in accordance with 8.3.2. (See annex D.)

8.3.2 Extraction procedure

Macerate the test portion prepared in 8.3.1 with 25 times 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*(HCl) = 0,14 mol/l (6.1.2) at (37 ± 2) °C which has 25 times the mass of the test portion.

Shake for 1 min. Check the acidity of the mixture. If the pH is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of *c*(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 (see 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* (see 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 under 10 e).

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

8.4 Natural or synthetic textiles

8.4.1 Test portion preparation

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

If the sample is not of a uniform material or colour, 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. (See annex D.)

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

Toys and toy components shall be first 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, 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. (See annex D.)

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

8.5.2 Extraction procedure

Place the 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 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 under 10 e).

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

8.6 Other materials, whether mass-coloured or not (see annex D)

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 greater than 10 mg. Where there is only between 10 mg and 100 mg of uniform material, report the mass of the test portion under 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 similar coating, follow the procedure in 8.1.1.

8.6.2 Extraction procedures

Extract the materials in accordance with 8.2.2, 8.3.2, 8.4.2 or 8.5.2, as appropriate. Report the method used under 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.