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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

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 181, *Safety of toys*.

This third edition cancels and replaces the second edition (ISO 8124-3:2010), which has been technically revised. It also incorporates the Amendments ISO 8124-3:2010/Amd.1:2014 and ISO 8124-3:2010/Amd.2:2018. The main changes to the previous edition are as follows:

— two detailed dewaxing methods have been introduced to replace the original one;

— an ICP-OES method for determination of the elements is given in Annex C as informative content.

A list of all parts in the ISO 8124 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The requirements of this document are based on the bioavailability of certain elements resulting from the use of toys, which 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, in the knowledge that in certain individual cases these values might be exceeded.

By combining the daily intake with the bioavailability values listed above, limits have been 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).

Safety of toys —

Part 3:
Migration of certain elements

WARNING — Persons applying this document should be familiar with laboratory practice for chemical analysis. This document does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices.

IMPORTANT — It is essential that the laboratory ensures that personnel have the competence to perform laboratory activities for which they are responsible.

1 Scope

1.1 This document specifies maximum acceptable levels and methods of sampling, extraction and determination 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 9.1);

— polymeric and similar material, including laminates, whether textile-reinforced or not, but excluding other textiles and non-woven textiles (see 9.2);

— paper and paperboard (see 9.3);

— natural, artificial or synthetic textiles (see 9.4);

— glass/ceramic/metallic materials, excepting lead solder when used for electrical connections (see 9.5);

— other materials, whether mass-coloured or not (e.g. wood, fibreboard, hardboard, bone and leather) (see 9.6);

— materials intended to leave a trace (e.g. the graphite materials in pencils and liquid ink in pens) (see 9.7);

— pliable modelling materials, including modelling clays and gels (see 9.8);

— paints to be used as such in the toy, including finger paints, varnishes, lacquers, glazing powders and similar material in solid or liquid form (see 9.9).

1.3 The requirements in this document apply to the following toys and toy components of toys and toy materials (see D.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 under 72 months of age;

— accessible coatings, irrespective of any age grading or recommended age labelling;

— accessible liquids, pastes and 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, for example boxes and containers, or unless they form part of the toy or have intended play value (see D.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 documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 8124-1:2018, *Safety of toys — Part 1: Safety aspects related to mechanical and physical properties*

ISO 8124-6:2018, *Safety of toys — Part 6: Certain phthalate esters in toys and children's products*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
base material
material upon which *coatings* (3.2) may be formed or deposited

3.2
coating
layers of material formed or deposited on the *base material* (3.1) 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* (3.7) with a sharp blade

3.3
method detection limit
MDL
three times the standard deviation of the result obtained in the method blank by the laboratory carrying out the analysis

3.4
mass-coloured material
material which has absorbed colouring matter without formation of a *coating* (3.2)

EXAMPLE Wood, fibreboard, hardboard, leather, bone and other porous substances.

3.5
paper
sheet formed by irregularly intervened cellulose fibres with a mass per unit area of 400 g/m^2 or less

Note 1 to entry: If paper with polymeric lamination, or other treatments which may be resistant to wetting, no longer presents the same properties as paper, then it is not treated as such.

[SOURCE: ISO 8124-1:2018, 3.46]

3.6
paperboard
sheet formed by irregularly intervened cellulose fibres with a mass per unit area over 400 g/m^2, excluding pressed wooden fibreboards such as medium density fibreboard (MDF), chipboard and materials with similar properties

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

Note 2 to entry: If paperboard with polymeric lamination, or other treatments which may be resistant to wetting, no longer present the same properties as paper, then they are not treated as such.

[SOURCE: ISO 8124-1:2018, 3.85]

3.7
scraping
mechanical process for removal of *coatings* (3.2) down to the *base material* (3.1)

3.8
toy material
accessible material present in a toy

3.9
method blank
aliquot of extraction solvent that is treated exactly as a sample including exposure to glassware, apparatus and conditions used for a particular test, but with no added sample

3.10
calibration blank
solution containing no analyte that is used to verify blank value

EXAMPLE 0,07 ± 0,005 mol/l hydrochloric acid solution (6.1).

3.11
instrument detection limit
IDL
three times the standard deviation of the result obtained by analysing calibration blank

3.12
calibration check solution
solution of known composition within the range of the calibration solutions, but prepared independently

4 Maximum acceptable levels

4.1 Specific requirements

See D.3.

Toys and parts of toys, as specified in Clause 1, are deemed to meet the requirements of this document when the adjusted value of migration of elements from them conform with the maximum limits given in Table 1 when tested in accordance with Clauses 8, 9 and 10.

4.2 Interpretation of results

See D.4.

Due to the precision of the methods specified in this document, an adjusted analytical result is required to take into consideration the results of interlaboratory trials. The analytical results obtained in accordance with Clauses 8, 9 and 10 shall be adjusted by subtracting the analytical correction in Table 2 to obtain an adjusted analytical result.

Materials are deemed to conform with the requirements of this document 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	60	25	250	50	25	90	25	500
Finger paint	10	10	350	15	25	25	10	50

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 as shown in Formula (1).

$$120 - \frac{120 \times 30}{100} = 120 - 36 \quad (1)$$

= 84 mg/kg.

This is deemed to be conforming with the requirements of this document (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 inductively coupled plasma optical emission spectrometry (ICP-OES) or other specified analytical methods with specified MDL.

6 Reagents

NOTE No recommendation is made for the reagents and materials necessary for carrying out elemental analyses within the MDL specified in 10.2.

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

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

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

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

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

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

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

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

7 Apparatus

NOTE No recommendation is made for the apparatus necessary for carrying out elemental analyses within the MDL specified in 10.2.

See D.5.

Normal laboratory apparatus and the following:

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

7.2 Means of measuring pH to proper accuracy without cross-contamination

The accuracy of pH measurement shall be cautiously considered to make sure the pH value of the mixture is in the range 1,0–1,5 (as specified in Clause 9). For example, when a pH measurement with an accuracy of ± 0,2 pH units is used, the range shall be changed to 1,2–1,3 after considering the uncertainty.

See D.5.1.

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

7.4 Centrifuge, capable of centrifuging at (5 000 ± 500) g[1)].

See D.5.2.

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

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

See D.5.3.

7.7 Soxhlet extractor, according to ISO 8124-6:2018, Figure C.1.

7.8 Solvent extractor, according to ISO 8124-6:2018, Figure C.2.

7.9 High retention filter paper, for example quantitative slow flow rate filter paper.

8 Selection of test portions

See D.6.

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

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, such as dot printing, patterned textiles or mass limitation reasons, precludes the formation of discrete specimens.

NOTE The requirement does not preclude the taking of test portions from materials used to manufacture the toy, provided they are representative of the final toy.

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

9 Preparation and extraction of test portions

NOTE A guideline for the choice of procedure to be used for the various toy materials is provided in Annex B.

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

9.1.1 Test portion preparation

Remove the coating from the laboratory sample by scraping (see 3.7) 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 (7.1).

If only between 10 mg and 100 mg of comminuted uniform coating is available, extract this in accordance with 9.1.2 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 Clause 11 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.

9.1.2 Extraction procedure

Using a container of appropriate size (7.6), mix the test portion prepared in 9.1.1 with 50 × its mass of an aqueous HCl solution at (37 ± 2) °C of *c*(HCl) 0,07 mol/l (6.1). [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) at (37 ± 2) °C.]

Shake for 1 min. Check the acidity of the mixture (7.2). If the pH is greater than 1,5, add dropwise, while shaking the mixture, an aqueous solution of *c*(HCl) approximately 2 mol/l (6.4) 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 (7.5) 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 (7.3) and, if necessary, by centrifuging at up to 5 000 *g* (7.4). 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 Clause 11 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*(HCl) = 1 mol/l (6.3). Report such stabilization in accordance with Clause 11 e).