

**MERCOSUR
STANDARD**

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**Safety of toys
Part 3: Migration of certain elements**



**MERCOSUR
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Foreword

The AMN – MERCOSUR Standardization Association – aims to promote and undertake the actions towards the development and harmonization of standards under the Southern Common Market – MERCOSUR, and is comprised by the National Standardization Agencies of the member countries.

The AMN performs its standards activity by means of the CSM – MERCOSUR Sectorial Committees – Which were set up for clearly defined action fields.

The Draft MERCOSUR Standards, prepared under the CSM, are submitted to national vote through the Standards National Agencies of member countries.

The acceptance as MERCOSUR Standard through MERCOSUR Standardization Association requires consensus approval by its members.



Introduction

This MERCOSUR Standard is the Part 3 of the Standard on the Safety of toys.

This standard has the following parts:

- Part1: General, 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: Security of electric toys.

The requirements of this part of MERCOSUR Standard 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 mg for antimony;
0.1 mg for arsenic;
25.0 mg for barium;
0.6 mg for cadmium;
0.3 mg for chromium;
0.7 mg for lead;
0.5 mg for mercury;
5.0 mg for selenium

For the interpretation of these values it was necessary to identify an upper limit for the ingestion of toy material. Very limited data is available for identifying this upper limit. As a working hypothesis, an average daily intake of 8 mg of toy material was adopted, taking into account that in some particular cases, such value may be higher.

Combining the daily intake with the bioavailability values listed above, limits were obtained for various elements in micrograms per gram (milligrams per kilogram) that are detailed on Table 1. The obtained values were determined to minimize children's exposure to such elements and to ensure analytical feasibility, taking into account limits achievable under normal manufacturing conditions (see Attachment C.1).



Safety of toys

Part 3: Migration of certain elements

Scope

1.1 This part of MERCOSUR standard establishes the requirements and test methods for migration of material for toys and shares of toys, except for materials not available (see Part 1 of this Standard), the following elements: antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium.

1.2 For the purpose of this part, toy packaging materials are not included, except for cases in which such packaging or materials are an integral part of the toy, thus having a playing value (see Attachment C).

1.3 Whenever necessary the toy shall be submitted to the appropriate tests specified in Part 1 of this Standard, before considering the accessibility of the parts.

1.4 The requirements are related to the migration of elements from the following toy materials:

Coatings such as paints, enamels, varnishes, printing, polymers, and similar coatings (see 8.1);

polymers and similar substances, including laminates, reinforced or not with textiles, but excluding other textiles (see 8.2);

paper and paperboard (see 8.3);

textiles, natural or synthetic (see 8.4);

Chrystal, ceramic, metallic materials, except lead solder used in electrical connections (see 8.5);

other materials, pigmented or not (for example, wood, paperboard, fiberboard, bone and leather) (see 8.6);

materials intended to produce a trace on a surface (for example, the graphite of a pencil and liquid ink from a ballpoint pen) (see 8.7);

malleable materials for modeling, including pastes and gels (see 8.8);

paints, included as such in toys, including finger paints, enamels, varnishes, lacquers enamelling powders and similar substances, in solid or liquid form. (see 8.9);

1.5 Toys and parts of toys that, on account of size, weight, accessibility, function or other characteristics exclude any risk of ingestion, inhalation or licking, considering the habitual or expected behavior of children, are not covered in this part of MERCOSUR Standard.

NOTE - For the purposes of this Standard, the criteria below are considered appropriate for the classification of toys that can be sucked, licked or swallowed:

All toys intended for food contact, cosmetic toys and writing tools;

Toys intended for children under six years of age, that is, all parts and accessible that may predictably come in contact with the mouth (see Attachment C).



Normative references

The following normative documents contain provisions which, through reference in this text, constitute requirements of this part of MERCOSUR Standard. The indicated editions were valid at the time of publication of this Standard. As every standard is subject to reviews, parties entering agreements based on this MERCOSUR Standard are encouraged to investigate the possibility of using the most recent editions of the normative documents listed below. Normative Agencies of member countries maintain updated information on latest editions at all times. NM 300-1:2002 – Safety of toys – Part 1: General, mechanical and physical properties

ISO 3696:1987¹⁾ – Water for analytical laboratory use – Specification and test methods

Definitions

For the purposes of this part of MERCOSUR standard, the following terms and definitions apply:

base material

material upon which coatings may be applied or deposited

coating

all layers of material applied 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, regardless of the way they have been applied to the toy, and which can be removed by scraping with a sharp blade

detection limit of a method

three times the standard deviation of the result obtained in the blank test using that method

mass colored materials

materials, such as wood, leather and other porous substances, which have absorbed coloring matter without formation of a coating

paper and cardboard

A maximum mass per surface area of 400 g/m² was established to classify materials under this category. Above this mass, materials are classified under “other materials” category, and may be heavy paperboards or fiberboards.

scraping

mechanical process for removal of coatings down to the base material

toy material

All accessible materials present in a toy



Requirements

1.6 Specific requirements

The migration of elements from toys and parts of toys specified in section 1, shall not exceed the limits shown on Table 1, when tested in accordance with sections 7, 8 and 9 (see Attachment C).

Table 1 — Maximum acceptable element migration from toy materials

| ELEMENT | | Sb | As | Ba | Cd | Cr | Pb | Hg | Se |
|---|---|----|----|------|----|----|----|----|-----|
| Maximum Migration of element in mg / kg from the toy material | Any material from toy mentioned in section 1, except: modeling paste, and finger paints | 60 | 25 | 1000 | 75 | 60 | 90 | 60 | 500 |
| | Modeling paste and finger paints | 60 | 25 | 250 | 50 | 25 | 90 | 25 | 500 |

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1.7 Interpretation of results

The analytical results obtained in accordance with the sections 7, 8 and 9 shall be adjusted by subtracting the correction coefficient indicated in table 2 to obtain adjusted analytical results.

Table 2 — Analytical correction

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

The materials are considered compatible with the requirements of this part of the Standard, if the adjusted analytical results are equal or smaller than the values on Table 1 (see Attachment C).

NOTE – Given the accuracy of the methods specified this standard, it is necessary to use the adjusted values in order to take inter-laboratorial test results into account (see Attachment C).

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 result is deemed as complying with the requirements of the Standard (maximum acceptable migration for lead as given on Table 1, is 90 mg/kg).

Principle

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



Reagents and apparatus

NOTE – No recommendations are made for the reagents, materials, and apparatus necessary for carrying out elemental analyses within the detection limits specified in Item 9.

1.8 Reagents

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

- 1.8.1 Hydrochloric acid solution, $c(\text{HCl})$ of approximately 0,07 mol/l.
- 1.8.2 Hydrochloric acid solution, $c(\text{HCl})$ of approximately 0,14 mol/l.
- 1.8.3 Hydrochloric acid solution, $c(\text{HCl})$ of approximately 1 mol/l.
- 1.8.4 Hydrochloric acid solution, $c(\text{HCl})$ of approximately 2 mol/l.
- 1.8.5 Hydrochloric acid solution, $c(\text{HCl})$ of approximately 6 mol/l.
- 1.8.6 n-heptane(C_7H_{16}); 99%.
- 1.8.7 Water of at least grade 3 purity, in accordance with ISO 3696.

1.9 Apparatus

Normal laboratory apparatus and:

- 1.9.1 Plain weave wire mesh stainless steel metal sieve, of nominal 0,5 mm aperture and tolerances as indicated on Table A.1 in Attachment A.
- 1.9.2 Means of measuring pH with an accuracy of $\pm 0,2$ pH units. Cross-contamination shall be prevented (see Attachment C).
- 1.9.3 Membrane filter, with pore size between 0,45 μm and 2,50 μm
- 1.9.4 Centrifuge, capable of centrifuging at $(5000 \pm 500)\text{g}^{(1)}$ (see Attachment C).
- 1.9.5 Means to agitate the mixture at a temperature of $(37 \pm 2) ^\circ\text{C}$.
- 1.9.6 A container set, with a net volume between 1.6 times and 5.0 times that of the volume of extracted hydrochloric acid (see Attachment C).



Selection of test samples

The sample for laboratory testing is a toy in the form in which it is sold, or is intended to be sold. Test samples are to be taken from accessible parts (see NM 300-1), from a single toy sample. Identical materials from different parts of the toy may be combined into a single test sample, but no samples from a different toy can be used. Test samples cannot combine more than one material, except when the physical separation (for example point serigraphic prints, printed fabrics) or a very limited mass of material makes it impossible to obtain discrete (see Attachment C).

The composition of a single sample of a material from different parts is accepted when such combination results from portions of up to four different colors, provided that the masses of each different color material are identical. In this case the migration limits indicated on Table 1 shall be divided by the number of colors and provided that the requirements established in section 9 of this Standard are met

NOTE - This requirement does not prevent obtaining samples from non accessible areas provided they are representative of the relevant material and the substrate on which it is deposited (see Attachment C).

Tests shall not be made with samples with a mass of less than 10 mg of available material.

Preparation and extraction of test samples

1.10 Coatings such as paint, varnish, lacquer, printing ink, polymer and similar coatings

1.10.1 Test sample preparation

Remove the coating from the laboratory sample by mechanical action (3.6) at room temperature and comminute it at a temperature not exceeding room temperature. Collect enough coating to obtain a test portion of preferably not less than 100 mg which will pass through a metal sieve of 0.5 mm aperture (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 according to 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.

1.10.2 Test method

In a container of appropriate size (6.2.6), mix the sample test prepared previously with 50 times its mass of an aqueous solution of hydrochloric acid $c(\text{HCl})$ of 0.07 mol / L (6.1.1) at $(37 \pm 2) ^\circ\text{C}$. If the test sample has a mass between 10 mg and 100 mg, mix the sample test with 5.0 ml this solution (6.1.1) to $(37 \pm 2) ^\circ\text{C}$.

Shake for 1 min and check the acidity of the mixture. If the pH is higher than 1.5, add drop by drop, while stirring the mixture, an aqueous solution of hydrochloric acid $c(\text{HCl})$ of approximately 2 mol / L (6.1.4) until the pH of the mixture is between 1.0 and 1.5. Protect the mixture from the light. Shake the mixture (6.2.5) at $(37 \pm 2) ^\circ\text{C}$ continuously for 1 h then let it rest for 1 h at $(37 \pm 2) ^\circ\text{C}$.

Then separate the solid parts from mixture, first by filtering using a filter (6.2.3) and, if necessary, by centrifuging at $5\,000\text{ g}^{(1)}$ (6.2.4). Perform the separation as soon as possible after the rest period. If the centrifuge is used, it shall not be for more than 10 minutes and it shall be informed according to 10 e).

If the resulting solutions are to be stored for more than one day of work before analysis, they shall be stabilized by adding hydrochloric acid, so that the concentration of the solution stored is approximately $c(\text{HCl}) = 1\text{ mol / L}$. Such stabilization shall be informed according to 10 e).



1.11 Polymers and similar materials, including laminates, textile reinforced or not with textiles, but excluding other textiles

1.11.1 Preparation of the test sample

Obtain a test sample with at least 100 mg of the polymer or similar material, avoiding heating it, and following the procedures below.

1.11.2 The sample shall be cut across the sections with the smallest cross sections, in order to obtain a test sample with the largest possible surface area for a given mass. None of the pieces shall have any dimension above 6 mm. If a laboratory test sample is not of a uniform material, sample tests must be obtained for each different material, with a mass larger than 10 mg. If there are between 10 and 100 mg of uniform material, the mass of the test sample shall be mentioned according to 10 e) and calculate the quantity of elements as if a 100 mg sample were used

1.11.3 Test method

Follow the procedure for extraction described in 8.1.2 using the test specimen prepared according with the item 8.2.1.

1.12 Paper and paperboard

1.12.1 Test sample preparation

Obtain a test sample of at least 100 mg.

If a laboratory test sample is not of a uniform material, sample tests must be obtained for each different material, with a mass larger than 10 mg. If there are between 10 and 100 mg of uniform material, the mass of the test sample shall be mentioned according to 10 e) and calculate the quantity of elements as if a 100 mg sample were used. If paper or cardboard to be tested is coated with paint, enamel, varnish, paint, printing, adhesive film or similar, the samples for testing shall also include parts or materials that are representative of the surface of the material, which shall be informed according to 10 e). The test sample is prepared according to 8.3.2 (see Attachment C).

1.12.2 Test method

Let the test sample soak according to 8.3.1 in 25 times its mass of water (6.1.7) in an appropriate container (6.2.6) at $(37 \pm 2)^\circ\text{C}$, so that the resulting mixture is homogeneous. Add to the mixture 25 times the original sample mass of aqueous solution of $c(\text{HCl}) = 0.14 \text{ mol / L}$ (6.1.2) at $(37 \pm 2)^\circ\text{C}$. Shake for 1 min and check the acidity of the mixture. If the pH is higher than 1.5, add drop by drop, while stirring the mixture, an aqueous solution of hydrochloric acid $c(\text{HCl})$ of approximately 2 mol / L (6.1.4) until the pH of the mixture is between 1.0 and 1.5. Protect the mixture from the light. Shake the mixture (6.2.5) at $(37 \pm 2)^\circ\text{C}$ continuously for 1 h then let it rest for 1 h at $(37 \pm 2)^\circ\text{C}$.

Then separate the solid parts from mixture, first by filtering using a filter (6.2.3) and, if necessary, by centrifuging at $5\,000 \text{ g}^{(1)}$ (6.2.4). Perform the separation as soon as possible after the rest period. If the centrifuge is used, it shall not be for more than 10 minutes and it shall be informed according to 10 e).

If the resulting solutions are to be stored for more than one day of work before analysis, they shall be stabilized by adding hydrochloric acid, so that the concentration of the solution stored is approximately $c(\text{HCl}) = 1 \text{ mol / L}$. Such stabilization shall be informed according to 10 e).



1.13 Natural or synthetic textiles

1.13.1 Preparation of the test sample

Obtain a test sample of no less than 100 mg, cutting the material to pieces which shall not have any dimension above 6 mm. (see Attachment C).

If the sample is not uniform with respect to material or color, other samples from each different material whose mass is greater than 100 mg. A sample with a mass between 10 and 100 mg will be part of the test sample obtained from the primary material. Samples taken from printed textiles shall be representative of the material as a whole (see Attachment C).

1.13.2 Test method

The method indicated in 8.12, using the prepared test sample according to 8.4.1.

1.14 Glass, Ceramics, metallic materials

1.14.1 Preparation of the test sample

Toys and their components shall first be subjected to appropriate tests according to NM 300-1. If the toy or one of its components fits entirely in the small parts cylinder, and contain glass, ceramics, or accessible metallic materials, they must be subjected to tests according to 8.5.2 after removal of any coatings as indicated in 8.1.1 (see Attachment C).

NOTE - Toys and components of toys that do not have glass, ceramics or metal accessible parts, are not subject to tests according to 8.5.2 (see Attachment C).

1.14.2 Test method

Place the toy or component in a 50 ml glass jar with nominal dimensions of 60 mm in height and 40 mm in diameter. A sufficient volume of aqueous solution of hydrochloric acid $c(\text{HCl}) = 0.07 \text{ mol / L}$ (6.1.1) at $(37 \pm 2) \text{ }^\circ\text{C}$ so as to completely cover the toy or component. The jar shall be covered and let rest for 2h, protecting it from light, at $(37 \pm 2) \text{ }^\circ\text{C}$.

NOTE – This jar may accommodate all the toys or components that fit into the small parts cylinder, indicated in NM 300-1.

Then solid parts are separated from the solution, first by decantation, followed by filtration with a filter (6.2.3) and, if necessary, by centrifugation at a maximum of $5\,000 \text{ g}^{(1)}$ (6.2.4) for no more than 10 minutes. If centrifugation is used, it shall be informed according to 10 e). The solids separation must be carried out immediately after the rest period.

If the resulting solutions are to be stored by more than one day of work before analysis, they shall be stabilized by adding hydrochloric acid, so that the concentration of the solution to be stored is approximately $c(\text{HCl}) = 1 \text{ mol / L}$. The stabilization must be informed according to 10 e).



1.15 Other materials pigmented or not (see Attachment C)

1.15.1 Preparation of the test sample

Obtain a test sample of at least 100 mg, according to 8.2.1, 8.3.1, 8.4.1 or 8.5.1, whichever is appropriate

If a laboratory test is not uniform in its material, other test samples must be obtained from each different material whose mass is greater than 10 mg. When the mass of uniform material is between 10 and 100 mg, the mass of the test sample shall be informed according to 10 e0, and the quantity of elements shall be calculated as if a 100 mg sample were used. If the material being tested is coated with paint, enamel, varnish, printing ink or similar material, the method indicated in 8.1.1 shall be followed.

1.15.2 Test method

Extract the materials in accordance with 8.2.2, 8.3.2, 8.4.2 or 8.5.2, whichever is appropriate (see Attachment C) The used method shall be informed according to 10 e).

1.16 Materials intended to produce a trace on a surface (mark)

1.16.1 Obtention and preparation of test sample of solid materials

Obtain a test sample, with a minimum mass of 100 mg cutting the material in pieces no larger than 6 mm.

A test sample shall be obtained from each material intended to produce traces that are present in the laboratory sample, whose mass is larger than 10 mg. When the mass is between 10 and 100 mg, the test sample mass shall be informed according to 10 e), and the quantity of corresponding elements shall be calculated as if a mass of 100 mg were used.

If the material contains any grease, oil, wax or similar materials, the test sample must be placed in a filter or hardened paper, and such substances shall be removed by using n-heptane or other suitable solvent for dissolvent extraction (6.1.6), before the sample is submitted to treatment according to 8.7.4. Analytical measurements shall be performed to assure that the extraction of such substances is quantitative. The nature of the solvent shall be informed according to 10 e).

1.16.2 Obtainance and preparation of test sample of liquid materials

Obtain a test sample of no less than 100 mg from the laboratory sample. The use of a suitable solvent is allowed to facilitate the extraction of such test sample.

A test sample shall be obtained from each material intended to produce traces that are present in the laboratory sample, whose mass is larger than 10 mg. When the mass is between 10 and 100 mg, the test sample mass shall be informed according to 10 e), and the quantity of corresponding elements shall be calculated as if a mass of 100 mg were used.

If the material is intended to solidify in normal use and contains grease, oil, wax or similar materials, the test sample must be allowed to solidify as it would in normal use. The resulting solid material shall be placed in a hardened paper filter and the grease, oil, wax or other similar materials shall be extracted by using n-heptane or any other suitable dissolvent (see 6.1.6) before test sample treatment according to 8.7.4. Analytical measurements shall be made to assure that the extraction of these substances is quantitative. The nature of the used dissolvent shall be informed according to 10 e).



1.16.3 Test procedure for samples that do not contain grease, oil, wax or similar materials

Using a container of appropriate size (6.2.6), mix the test sample prepared according with 8.7.1 or 8.7.2 with 50 times its mass of an aqueous solution of hydrochloric acid $c(\text{HCl})$ 0.07 mol / L (6.1.1) at $(37 \pm 2)^\circ\text{C}$. For a sample test with mass between 10 mg and 100 mg, mix the sample test with 5.0 ml this solution at $(37 \pm 2)^\circ\text{C}$.

Shake for 1 min. Check the acidity of the mixture. If the test sample contains large quantities of alkaline material, usually in the form of calcium carbonate, adjust the pH between 1.0 and 1.5 with hydrochloric acid solution $c(\text{HCl})$ about 6 mol / L (6.1.5) to avoid a super dilution. The volume of hydrochloric acid used, and its relation with the volume of the solution shall be informed according to 10 e).

If the quantity of alkaline substance in the mixture is not significant, and if the pH is greater than 1.5, an aqueous solution of hydrochloric acid $c(\text{HCl})$ about 2 mol / L (6.1.4) shall be added drop by drop while stirring until the pH is between 1.0 and 1.5. Stir the mixture continuously at $(37 \pm 2)^\circ\text{C}$ (6.2.5) for 1 hour and then let it rest for 1 hour at $(37 \pm 2)^\circ\text{C}$, protecting it from light.

1.16.4 Test procedure for samples containing grease, oil, wax or similar materials

The test sample prepared as according to 8.7.1 or 8.7.2 remaining in the hardened paper filter is placed in a mass of water (6.1.7) equivalent to 25 times the original mass of the material, at $(37 \pm 2)^\circ\text{C}$, and let it soak until a homogeneous mixture is obtained. The mixture is then quantitatively transferred to an appropriate size container (6.2.6). A hydrochloric acid aqueous solution $c(\text{HCl})$ 0.14 mol / L (6.1.2) at $(37 \pm 2)^\circ\text{C}$ with a mass of 25 times the mass of the original test sample is added..

If the mass of the test sample is between 10 and 100mg, it should be left to soak in 2.5 ml of water (6.1.7). The mixture is quantitatively transferred to an adequate size container (6.2.6), and 2.5 ml aqueous solution of hydrochloric acid $c(\text{HCl})$ 0.14 mol / L (6.1.2) at $(37 \pm 2)^\circ\text{C}$ is added to the mixture.

Shake for 1 min. Check the acidity of the mixture. If the test sample contains large quantities of alkaline material, usually in the form of calcium carbonate, adjust the pH between 1.0 and 1.5 with hydrochloric acid solution $c(\text{HCl})$ about 6 mol / L (6.1.5) to avoid a super dilution. The volume of hydrochloric acid used, and its relation with the volume of the solution shall be informed according to 10 e).

If the quantity of alkaline substance in the mixture is not significant, and if the pH is greater than 1.5, an aqueous solution of hydrochloric acid $c(\text{HCl})$ about 2 mol / L (6.1.4) shall be added drop by drop while stirring until the pH is between 1.0 and 1.5. Stir the mixture continuously at $(37 \pm 2)^\circ\text{C}$ (6.2.5) for 1 hour and then let it rest for 1 hour at $(37 \pm 2)^\circ\text{C}$, protecting it from light.

NOTE - The volume of the solution of HCl $c(\text{HCl})$, 0.7 mol / L or $c(\text{HCl})$, 0.14 mol / L, depending on the case, is calculated as a function of test sample max before the removal of wax, grease, oil or similar materials.

Without delay, separate the solids from solution, primarily by filtration using a filter (see 6.2.3) and, if necessary, by centrifugation at $5000\text{ g}^{(1)}$ (see 6.2.4). The separation must be carried out as soon as possible after the rest period. If centrifugation is used, it should last no more than 10 minutes, and it shall be informed according to 10 e).

If the resulting solutions are to be stored for longer than one day of work before analysis, stabilize them by adding hydrochloric acid until the concentration of the solution reaches approximately $c(\text{HCl}) = 1\text{ mol / L}$. The stabilization shall be informed according to 10 e)



1.17 Malleable materials for modeling, including modeling pastes and gels

1.17.1 Preparation of the test sample

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

A test sample shall be taken from each of the different materials in the laboratory sample. Get a sample to be tested for each material different sample in the laboratory.

If the material contains any grease, oil, wax or similar materials, the test sample must be placed in a filter or hardened paper, and such substances shall be removed by using n-heptane or other suitable solvent for dissolvent extraction (6.1.6), before the sample is submitted to treatment according to 8.8.3. Analytical measurements shall be performed to assure that the extraction of such substances is quantitative. The nature of the solvent shall be informed according to 10 e).

1.17.2 Test procedure for samples that do not contain grease, oil, wax or similar materials

Place test sample in an appropriate size container (6.2.6) after crumbling it if necessary. According with 8.8.1 mix the test sample with 50 times its mass of an aqueous solution of hydrochloric acid $c(\text{HCl})$ 0.07 mol / L (6.1.1) at $(37 \pm 2)^\circ\text{C}$.

Shake for 1 min. Check the acidity of the mixture. If the test sample contains large quantities of alkaline material, usually in the form of calcium carbonate, adjust the pH between 1.0 and 1.5 with hydrochloric acid solution $c(\text{HCl})$ about 6 mol / L (6.1.5) to avoid a super dilution. The volume of hydrochloric acid used, and its relation with the volume of the solution shall be informed according to 10 e).

If the quantity of alkaline substance in the mixture is not significant, and if the pH is greater than 1.5, an aqueous solution of hydrochloric acid $c(\text{HCl})$ about 2 mol / L (6.1.4) shall be added drop by drop while stirring until the pH is between 1.0 and 1.5. Stir the mixture continuously at $(37 \pm 2)^\circ\text{C}$ (6.2.5) for 1 hour and then let it rest for 1 hour at $(37 \pm 2)^\circ\text{C}$, protecting it from light.

Protect the mixture from light. Stir the mixture continually at $(37 \pm 2)^\circ\text{C}$ (6.2.5) by 1 hour and then let it rest for 1 hour at $(37 \pm 2)^\circ\text{C}$.

1.17.3 Test procedure for samples containing grease, oil, wax or similar materials

Take the test sample prepared according to 8.8.1, remaining in the hardened paper filter. Let the material soak in a mass of water (see 6.1.7) at $(37 \pm 2)^\circ\text{C}$, 25 times the original mass of the material, until the mixture is homogeneous. The mixture is then totally transferred to an adequate size container (see 6.2.6). An aqueous solution of hydrochloric acid $c(\text{HCl})$, 0.14 mol / L (6.1.2) at $(37 \pm 2)^\circ\text{C}$ 25 times the mass of the original test sample.

Shake for 1 min. Check the acidity of the mixture. If the test sample contains large quantities of alkaline material, usually in the form of calcium carbonate, adjust the pH between 1.0 and 1.5 with hydrochloric acid solution $c(\text{HCl})$ about 6 mol / L (6.1.5) to avoid a super dilution. The volume of hydrochloric acid used, and its relation with the volume of the solution shall be informed according to 10 e).

If the quantity of alkaline substance in the mixture is not significant, and if the pH is greater than 1.5, an aqueous solution of hydrochloric acid $c(\text{HCl})$ about 2 mol / L (6.1.4) shall be added drop by drop while stirring until the pH is between 1.0 and 1.5. Stir the mixture continuously at $(37 \pm 2)^\circ\text{C}$ (6.2.5) for 1 hour and then let it rest for 1 hour at $(37 \pm 2)^\circ\text{C}$, protecting it from light.

NOTE - The volume of hydrochloric acid solution $c(\text{HCl})$, 0.07 mol / L or 0.14 mol / L, as appropriate, is calculated as a function of the test sample mass before the removal of wax, grease, oil or other similar materials.

Without delay, separate the solids from solution, primarily by filtration using a filter (see 6.2.3) and, if necessary, by centrifugation at 5000 $\text{g}^{(1)}$ (see 6.2.4). The separation must be carried out as soon as possible after the rest period. If centrifugation is used, it should last no more than 10 minutes, and it shall be informed according to 10 e).



If the resulting solutions are to be stored for longer than one day of work before analysis, stabilize them by adding hydrochloric acid until the concentration of the solution reaches approximately $c(\text{HCl}) = 1 \text{ mol / L}$. The stabilization shall be informed according to 10 e)

1.18 Paints, including finger paints, lacquers, enameling powders, and similar materials in liquid or solid form

1.18.1 Preparation of test samples from materials in solid form

Obtain a test sample of no less than 100 mg from the laboratory sample by scraping it from the surface and cutting it down to fragments with dimensions no greater than 6 mm.

A test sample shall be obtained from each material intended to produce traces that are present in the laboratory sample, whose mass is larger than 10 mg. When the mass is between 10 and 100 mg, the test sample mass shall be informed according to 10 e), and the quantity of corresponding elements shall be calculated as if a mass of 100 mg were used.

If the material contains any grease, oil, wax or similar materials, the test sample must be placed in a filter or hardened paper, and such substances shall be removed by using n-heptane or other suitable solvent for dissolvent extraction (6.1.6), before the sample is submitted to treatment according to 8.9.4. Analytical measurements shall be performed to assure that the extraction of such substances is quantitative. The nature of the solvent shall be informed according to 10 e). If the sample test is obtained by scraping, grind the test sample so that the material can pass through a metal sieve with 0.5 mm mesh (6.2.1).

1.18.2 Preparation of test samples from materials in liquid form

Obtain a test sample from the laboratory sample with no less than 100 mg. The use of a suitable solvent to facilitate the obtainance of test material is allowed. A test sample shall be obtained from each material present in the laboratory sample, whose mass is larger than 10 mg. When the mass is between 10 and 100 mg, the test sample mass shall be informed according to 10 e), and the quantity of corresponding elements shall be calculated as if a mass of 100 mg were used.

If the material is intended to solidify in normal use and contains grease, oil, wax or similar materials, the test sample must be allowed to solidify as it would in normal use. The resulting solid material shall be placed in a hardened paper filter and the grease, oil, wax or other similar materials shall be extracted by using n-heptane or any other suitable dissolvent (see 6.1.6) before test sample treatment according to 8.9.4. Analytical measurements shall be made to assure that the extraction of these substances is quantitative. The nature of the used dissolvent shall be informed according to 10 e). **Test procedure for samples that do not contain grease, oil, wax or similar materials**

Follow the procedure described in 8.7.3, using the test samples prepared in accordance with 8.9.1 or 8.9.2.

Test procedure for samples containing grease, oil, wax or similar materials

Take the test sample prepared according to 8.9.1 or 8.9.2, remaining in the hardened paper filter. Let the material soak in a mass of water (see 6.1.7) at $(37 \pm 2)^\circ\text{C}$, 25 times the original mass of the material, until the mixture is homogeneous. The mixture is then totally transferred to an adequate size container (see 6.2.6). An aqueous solution of hydrochloric acid $c(\text{HCl})$, 0.14 mol / L (6.1.2) at $(37 \pm 2)^\circ\text{C}$ 25 times the mass of the original test sample.

Shake for 1 min. Check the acidity of the mixture. If the test sample contains large quantities of alkaline material, usually in the form of calcium carbonate, adjust the pH between 1.0 and 1.5 with hydrochloric acid solution $c(\text{HCl})$ about 6 mol / L (6.1.5) to avoid a super dilution. The volume of hydrochloric acid used, and its relation with the volume of the solution shall be informed according to 10 e).

If the quantity of alkaline substance in the mixture is not significant, and if the pH is greater than 1.5, an aqueous solution of hydrochloric acid $c(\text{HCl})$ about 2 mol / L (6.1.4) shall be added drop by drop while stirring until the pH is between 1.0 and 1.5. Stir the mixture continuously at $(37 \pm 2)^\circ\text{C}$ (6.2.5) for 1 hour and then let it rest for 1 hour at $(37 \pm 2)^\circ\text{C}$, protecting it from light.



NOTE - The volume of hydrochloric acid solution $c(\text{HCl})$, 0.07 mol / L or 0.14 mol / L, as appropriate, is calculated as a function of the test sample mass before the removal of wax, grease, oil or other similar materials.

Without delay, separate the solids from solution, primarily by filtration using a filter (see 6.2.3) and, if necessary, by centrifugation at 5000 g^1 (see 6.2.4). The separation must be carried out as soon as possible after the rest period. If centrifugation is used, it should last no more than 10 minutes, and it shall be informed according to 10 e).

If the resulting solutions are to be stored for longer than one day of work before analysis, stabilize them by adding hydrochloric acid until the concentration of the solution reaches approximately $c(\text{HCl}) = 1 \text{ mol / L}$. The stabilization shall be informed according to 10 e)

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Determination of quantity of migrated elements

In order to determine the contents of elements listed in Item 1, methods having a maximum detection limit of 1/10 of the values to be determined, shall be used (see 4.1, table 1). The detection limit (of a method) is estimated to be 3 times the standard deviation of the blank test, according to the way it is measured at the laboratory carrying out the analysis from toy materials.

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

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 part of the (NM 300-3) Standard;
- c) the methods used for determining the quantity of each migrated element, and the detection limit, if different from the requirements in section 9;
- d) the results of tests (see 4.2) expressed in milligrams of the element by kg of material, indicating that the result refers to the soluble element;
- e) details of the procedure used, in accordance with the requirements in section 8;
- f) any deviation, by previous agreement or otherwise, from the preparation and extraction procedures specified;
- g) date of the test.



Attachment A
(normative)

Sieve requirements

Table A.1 – Sieve dimensions and tolerances

Dimensions in millimeters

| 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 |



Attachment B
(informative)

Selection of procedure

The diagram in figure B.1 is a guideline for the choice of procedure to be used for the various toy materials.

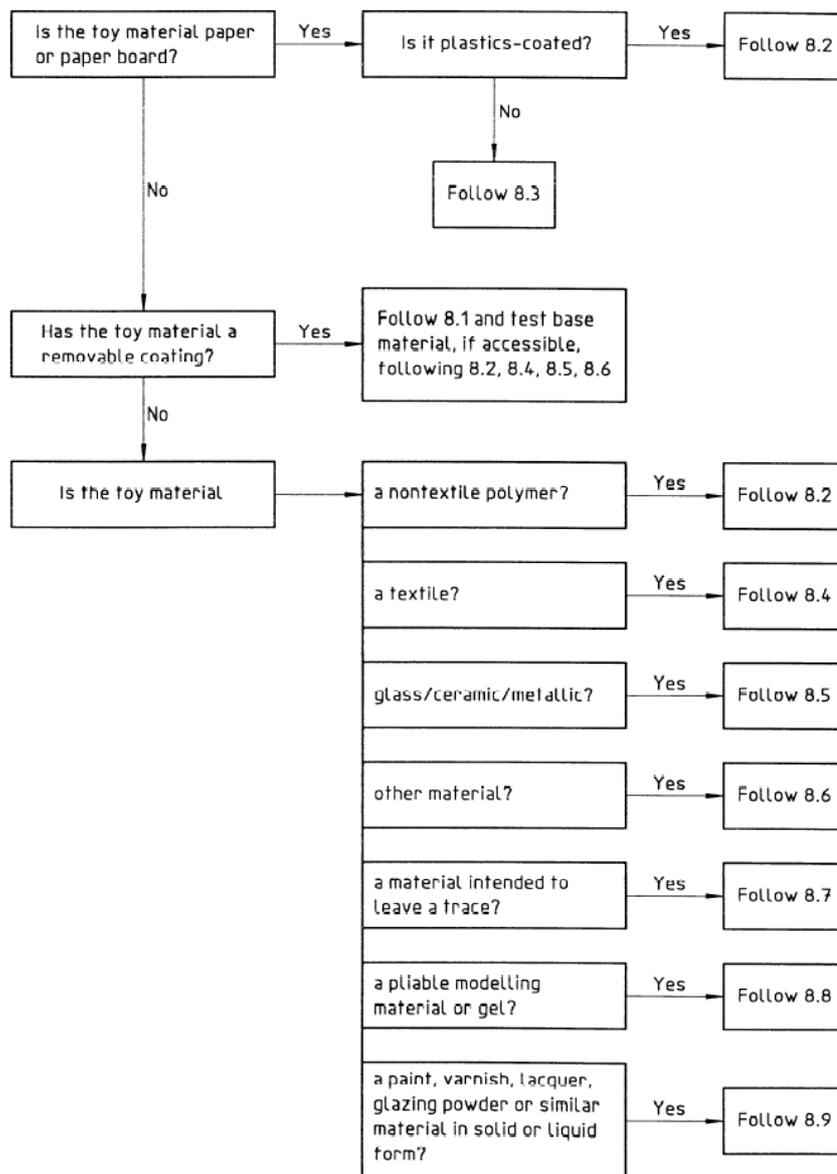


Figure B.1 - Guidelines for choosing the procedure for preparation and extraction of test portions



Attachment C (informative)

Context and justifications for the requirements and test methods mentioned in this part of the Standard

C.1 Introduction

The definition of "bioavailability" according to MERCOSUR Resolution for Safety of Toys (see MERCOSUR Resolution 54/92) implies the inclusion of test methods to determine the migration levels of soluble elements from a toy material.

The approach using total migrated element determination was discarded for the following reasons.

- a) the above mentioned resolution indicates bioavailability limits, and to date there has been no link between the availability of an element in a toy material, and the total content of such element in the material, when extractions are performed by means of simulated gastric solutions;;
- b) In certain cases, such as the one of barium sulfate, 2% can be included in products to make them radio opaque. Such use for barium should be excluded in the case of toys, or it should be object of a separate Standard.;
- c) cadmium compounds can be used as stabilizers in plastics such as polyvinylchloride (PVC). Under normal conditions, these compounds are not soluble in simulated gastric solutions. Therefore, if total elements were to be determined as an object of this Standard, there should be a justification for its use in the requirements of the Standard. This is also the case with selenium, which may be present as a constituent of insoluble pigments, etc.. (See also C.4).

C.2 Field of application

C.2.1 Packaging (see 1.2)

The words "except for cases in which such packaging or materials are an integral part of the toy" means, for example, boxes containing puzzles, or packaging in which the instructions are included in the case of games, etc., but, taking into account the second paragraph of the note of 1.5 which limits these toys for children under six years of age. It does not refer, for example, to the blisters containing simple instructions.

C.2.2 Note on scope (see 1.5)

This note is intended to indicate an approach to the decision on what toys, or toy components, are excluded from this part of the Standard because of characteristics that render them unlikely to present a risk of injury from the ingestion of materials containing toxic elements.

This was considered a logical approach for many reasons, including:

as children get older, the tendency for them to place toys/toy materials in their mouths is reduced and therefore the risk of the ingestion of toxic elements is reduced;

the larger the toy or the less accessible the material, the lower the risk of ingestion of toxic elements.

It was therefore considered that all toys which might 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 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 $c(\text{HCl}) = 0,07 \text{ mol/l}$ between 400 mg/kg and 600 mg/kg as expressed on the mass of toy material taken as a sample. This level is such that, due to the statistical uncertainty of the determination, acceptance or rejection could not be established.

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 barium migration of 500 mg/kg from toy materials was not consistent with 25,0 $\mu\text{g/day}$ of bioavailability and the 8 mg/d of toy material intake; 25,0 μg corresponds to a migration limit of 3125 mg/kg. Evidently, the 500 mg/kg limit was consciously selected in spite of the "theoretical" 3125 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 50,0 μg , not for toxicological reasons, but "to reduce the avoidable input burden on the body".

C.4 Statistical uncertainty of the testing 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.

Because of the way "bioavailability" is defined in the Resolution on the safety of toys, the methods on this section measure the migration of **soluble** elements from a toy material. With this approach, the analytical result is dependent upon 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 EN 71-3:1988 taken from a 1987 European interlaboratory survey 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 approximately three times higher if adjusted to a 95 % confidence level.

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

There is no direct relationship between the actual total element content of a toy material and the soluble migration of that element under standard test conditions. Therefore, measuring the total element content and converting the result to obtain a soluble element value is not an answer to this problem. Setting maximum total element limits is a possibility, but this would require an amendment to the MERCOSUR Resolution No. 54/92 on the safety of toys (see also C.1).

Since 1988, the procedure for testing of paint coatings applied on toys has been thoroughly investigated to determine which parameters significantly affect the results. The most critical parameters are 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 procedure for scraping and comminution to collect a paint test portion of particle size 300 μm to 500 μm was proposed as a revision to the test operative procedure. An European interlaboratory trial was conducted in 1993 with 29 participating laboratories to compare the amended procedure with that in NM 300-4.



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

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

The trial confirmed that the use of 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) was more widely used by laboratories in this occasion, 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 fall 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 techniques for scraping the paint off toys, collecting the portion that passes through a 500 µm sieve and determining the soluble-element concentration of the filtrate. To achieve consistent interpretation of results, a correction factor for each element and applicable to all instrumental techniques has been introduced. These are taken from the precision data in NM 300–4 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 to ensure the safety of children.

For the future, it is recommended that laboratories check and compare their performance of the test procedure by using reference materials and participating in control program.

C.5 Apparatus (see 6.2)

C.5.1 Plain weave wire cloth stainless steel sieve (see 6.2.1)

See indicated in C.4.

C.5.2 Means of measuring pH (see 6.2.2)

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

C.5.3 Centrifuge (see 6.2.4 and 8)

This new sub item specifies the performance requirements of the centrifuge. Item 8 specifies centrifuging limits and the amount of time permitted for centrifuging (up to 10 min) and requires this to be reported under 10 e). The latter is necessary, as centrifuging has been reported to increase the extraction of barium.

C.5.4 Choice of containers (see 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.6 Selection of test portions (see section 7)

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

C.7 Paper and paperboard (see 8.3)

C.7.1 Test portion preparation

Paper and paper 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 must include representative parts of the surface. This procedure has been adopted because, in the practical situation of a child chewing paper or paper board, preferential removal of a coating is unlikely and the substrate is equally important.

C.8 Natural or synthetic textiles (see 8.4)

C.8.1 Test portion preparation (see 8.4.1)

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

C.9 Glass, ceramics, metallic materials (see 8.5)

C.9.1 Test portion preparation (see 8.5.1)

Toys or components which do not fit entirely within the "small parts cylinder" of NM 300-1 are not tested because there is no hazard from ingestion and no significant extraction occurs with a saliva simulator. The small parts cylinder is used to assess the size of toys/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 NM 300-1 are not tested in accordance with 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 complete removal of the partial coating in accordance with the method given in 8.1.1. This procedure is a compromise, as only a single toy may be taken as a sample as specified in Item 7 of this Standard.

C.10 Other materials, pigmented or not (see 8.6)

This subitem applies to pigmented materials and other materials which are not colored, such as wood, fiberboard, leather and bone, etc. which may have received some other treatment, but were not covered by NM 300-4.



Attachment D
(informative)

References

For the study supporting this Standard, the following documents were consulted:

ISO INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO 8124-3:1997. Safety of toys. Part 3: Migration of certain elements.

AENOR - ASOCIACION ESPAÑOLA DE NORMALIZACIÓN Y CERTIFICACIÓN

UNE-EN 71-3 :1996. Seguridad de los juguetes. Parte 3: Migración de ciertos elementos.

The present document was translated into English and revised by independent translators

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Synthesis of the study phase

MERCOSUR Standard project 04:00-01-3

Safety of toys. Part 3: Migration of certain elements

1 INTRODUCTION

This part of this MERCOSUR Standard establishes the requirements and the test methods for migration from toy materials or parts of toys except non accessible (see Part 1 of this Standard), for the following elements: Antimony, Arsenic, Barium, Cadmium, Chrome, Lead, Mercury and Selenium.

This MERCOSUR Standard was developed by CSM 04 - Sectoral Mercosur Committee for Toys.

The base text for the MERCOSUR Standard 04:00-01-4 draft was prepared by (IRAM) in Argentina

2 SPECIALIZED COMMITTEE

This Standard was prepared by CSM 04 – Toys, and the Technical Secretary of CSM 04 was performed by IRAM.

The active members that participated in the preparation of this document were:

ABNT – Associação Brasileira de Normas Técnicas

INTN – Instituto Nacional de Tecnología y Normalización

IRAM – Instituto Argentino de Normalización

UNIT – Instituto Uruguayo de Normas Técnicas

3 PREVIOUS HISTORY

ISO-INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ISO 8124-3:1997- Safety of toys. Part 3: Migration of certain elements

AENOR- ASOCIACIÓN ESPAÑOLA DE NORMALIZACIÓN Y CERTIFICACIÓN

UNE-EN 71-3:1997 Seguridad de los juguetes. Parte 3: Migración de ciertos elementos.

COPANT- Comisión PANAMERICANA DE NORMAS TÉCNICAS

COPANT 1657 Parte 3:1999 – Seguridad de los juguetes. Migración de ciertos elementos

4 CONSIDERATIONS

NM-300-3:2002



The base text for the MERCOSUR Standard 04:00-01-3 was prepared by Argentina, based on the ISO 8124-3:1997.

It was submitted to the standardization agencies of the MERCOSUR member countries on September 17, 2001, for analysis by the Study Committees.

The draft was discussed in the technical meeting carried out in Buenos Ayres from October 29th to October 31st, 2001, in which form changes were made, and approved as a MERCOSUR Standard Draft.

It was submitted to vote in the CSM 04 in the period of 01/01/2002 to 03/31/2002.

During the voting period, approving vote was received from IRAM (Argentina) and ABNT (Brazil) with observations regarding form, which were accepted and incorporated to the draft. UNIT (Uruguay) and INTN (Paraguay) refrained from voting.

Thus, the Draft was approved as Proposed MERCOSUR Standard.

The Draft was sent to AMN, according to the established in the MERCOSUR Standard Elaboration Procedures, for edition and approval as MERCOSUR Standard NM 300-3, in November, 2002.

The present document was translated into English and revised by independent translators.