GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 97.200.50

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GB/T 37647-2019

Toy and children product - General principles for migration test of certain elements

玩具及儿童用品特定元素的迁移试验通则

Issued on: June 04, 2019 **Implemented on: January 01, 2020**

Issued by: State Administration for Market Regulation;
Standardization Administration of the People's Republic of China.

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Toy and children product - General principles for migration test of certain elements

1 Scope

This Standard specifies the sampling method, sample preparation and sample extraction method for the migration test of certain elements in toy and children product in the simulated human environment.

This Standard applies to the pretreatment of migration test of certain elements, such as aluminum, antimony, arsenic, barium, boron, cadmium, chromium, cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, zinc, in toy and children product in the simulated human environment (including sweat, saliva, and gastric juice environments). Migration tests of other certain elements can be performed with reference to this Standard after verification.

This Standard does not apply to the toy or children product which is clearly excluded from the possibility of being sucked, licked, chewed, swallowed or exposed to the skin for a long term, due to its accessibility, function, mass, size or other characteristics, in consideration of children's normal use and foreseeable behavior.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB 6675.1-2014, Toys safety - Part 1: Basic code

GB 6675.2, Safety of toys - Part 2: Mechanical and physical properties

GB 6675.4-2014, Safety of toys - Part 4: Migration of certain elements

GB/T 6682, Water for analytical laboratory use - Specification and test methods

3 Terms and definitions

Terms and definitions determined by GB 6675.1-2014, GB 6675.4-2014 and the following ones are applicable to this document. For ease of use, some of the

3.8 Reasonably foreseeable abuse

The possible way of use, which uses toy and children product in ways that are not recommended by the supplier, but may occur under normal circumstances, including the normal free behavior of children by combining toys and children products.

Examples: dismantle, drop, or use toy and children product in non-recommended ways.

Note: Rewrite GB 6675.1-2014, definition 3.17.

3.9 Sample area

The area of the test sample, which is immersed in the test solution, that is in contact with the solution and is not covered.

3.10 Base material

The material, on which coating can form or adhere to the surface.

[GB 6675.4-2014, definition 3.1]

3.11 Coating

All material layers that are formed or attached to the base material of the toy and children product.

Examples: paint, varnish, lacquer, ink, polymer, metal particle or other similar substances that are attached to the base material.

Note: Rewrite GB 6675.4-2014, definition 3.2.

3.12 Paper and paperboard

Paper and paperboard whose maximum mass per unit area is not more than 400 g/m^2.

Note: paper and paperboard whose mass per unit area exceeds 400 g/m^2 shall be treated as "other materials", and may also be fiberboard or cardboard.

[GB 6675.4-2014, definition 3.5]

3.13 Scraping

The mechanical process of separating the coating from the base material, which shall not scrap the base material.

[GB 6675.4-2014, definition 3.6]

5.5 Ammonia water: the mass fraction is 25%, ρ = 0.91 g/mL.

5.6 Dilute ammonia water: the mass fraction is 1%.

5.7 Sodium hydroxide (NaOH): c (NaOH) ≈ 0.1 mol/L.

5.8 Magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).

5.9 Calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$).

5.10 Dipotassium hydrogen phosphate trihydrate ($K_2HPO_4 \cdot 3H_2O$).

5.11 Potassium carbonate (K_2CO_3).

5.12 Potassium chloride (KCl).

5.13 Hydrochloric acid: the mass fraction is 37%.

5.14 N-heptane: chemically pure; the mass fraction is not less than 99%.

5.15 Hydrochloric acid solution: c (HCl) = (0.07 ± 0.005) mol/L.

5.16 Hydrochloric acid solution: c (HCl) = (0.14 ± 0.010) mol/L.

5.17 Hydrochloric acid solution: c (HCl) ≈ 2 mol/L.

5.18 Hydrochloric acid solution: c (HCl) ≈ 6 mol/L.

5.19 Hydrochloric acid solution: the mass fraction is 1%.

5.20 Unless otherwise specified, use only analytical reagents or reagents above the grade.

6 Instruments

6.1 Test sieve: plain stainless-steel wire mesh sieve; the rated aperture is 0.5 mm.

6.2 pH meter: the accuracy is not less than ± 0.1pH unit; it shall be prevented from cross-contamination.

6.3 Membrane filter: the pore size is 0.22 μm and 0.45 μm.

6.4 Centrifuge: the centrifugal capacity is (5 000 ± 500) g (g = 9.806 65 m/s^2).

6.5 Constant-temperature oscillator: the temperature is constant at (37 ± 2) °C during oscillation; the oscillation frequency accuracy is not less than ±5 times/min.

physical separation methods (those caused by reasons such as dot dyeing, printing textiles or quality restrictions).

Note: It does not exclude the acquisition of any form of reference sample, as long as the reference sample can represent the relevant toy and children product material and the basic materials that are attached to them as specified above.

If the material mass is 10 mg ~ 100 mg, it shall be processed and calculated as 100 mg of test sample. The sample whose mass is less than 10 mg can be exempted from testing or tested by area method.

7.3.2 Sample preparation

7.3.2.1 Coating

At room temperature, adopt the method of scraping to obtain coating from the sample of toy and children product; pulverize the sample under the condition that does not exceed the ambient temperature. Obtain not less than 100 mg of coating test sample as much as possible from the materials that pass through a test sieve whose pore size is 0.5 mm (see 6.1).

For coatings that cannot be pulverized due to their own characteristics (such as elastic/ plastic paint), transfer the test sample directly from the sample without pulverizing the coating.

7.3.2.2 Other materials

Try to remove not less than 100 mg of test sample as much as possible; avoid material heating when removing. The test sample shall be cut from the smallest thickness of the material section, so as to ensure that the ratio of the test sample area to the test sample mass is as large as possible. The dimensions of each test sample in any direction shall not be greater than 6 mm in the uncompressed state.

If the material is spot-dyed or printed textile, the removed test sample shall be a representative sample of the overall material.

If there is a coating on the to-be-tested material, firstly remove the coating on the material according to the sampling procedure of 7.3.2.1; then, perform sampling on the base material.

If the material is liquid, no processing such as shredding is required; take samples directly.

7.3.3 Sample extraction

7.4.2.1 Coating

The base material and coating shall not be separated when preparing the test sample. When calculating the sample area, only calculate the area that is covered by the coating. If the sample is covered by the coating only on one side, only count the area of one side. The sample area of the taken test sample shall be larger than 1 cm^2 as far as possible.

When taking a sample, cut the test sample from the minimum thickness of the base material section as far as possible, to ensure that the area of the base material is as small as possible, so as to reduce the impact on the coating test.

For the sample which is covered with only one side of the coating, during the sample extraction process, certain elements in the extraction solution not only originate from the to-be-tested coating sample, but also from the base material, and the test results may be stricter than actual conditions.

When testing the coating sample, in order to avoid being affected by the base material, the non-tested surfaces can be wax-sealed.

7.4.2.2 Other materials

Remove a test sample of not less than 1 cm^2 as far as possible; avoid heat or pressure on the material when removing. For the base material that is covered with a coating on the surface, use mechanical methods to remove the coating before preparing the sample.

Paints, coatings, and plating shall not be considered as barriers that render components that contain certain elements in toy and children product inaccessible.

Considering that the incision will affect the test results, a complete sample shall be selected when preparing the sample. When cutting is required, choose the smallest thickness, as far as possible, for cutting. When the sample thickness is less than or equal to 0.5 mm, take the area of one side of the sample as the sample area; when the sample thickness is greater than 0.5 mm and less than or equal to 2 mm, take the sum of the areas of the front and back of the sample as the sample area; when the sample thickness is greater than 2 mm, take the sum of the areas of the front and back of the sample and the area of its side as the sample area.

For the sample that has inconsistent front and back materials, during the simultaneous test, only calculate the area of the accessible part of the to-be-tested material. In this case, the migrated certain elements may be from non-tested materials; therefore, the test results may be stricter than the actual conditions.

centrifuge (see 6.4) to separate. The centrifugation time shall not exceed 10 minutes, which shall be stated in the report.

9 General principles for gastric juice migration test model

9.1 Overview

Use a certain volume of simulated gastric juice (see 9.2) to process the sample under specific migration conditions. See Appendix C for technical information on the preparation of the gastric juice migration test model.

9.2 Simulated gastric juice preparation

Take 900 mL of water (see 5.1) into a 1 000 mL conical flask; add 5.81 mL of hydrochloric acid (see 5.13); stir well; transfer the solution to a 1 000 mL volumetric flask; add water (see 5.1) to fix-volume to 1 000 mL. Use standard anhydrous sodium carbonate or other standard-calibrated solutions to titrate, to obtain accurate hydrochloric acid solution concentration. The concentration shall be (0.07 ± 0.005) mol/L. This solution is a simulated gastric juice.

If the mass fraction of the used concentrated hydrochloric acid is not 37%, the volume of added hydrochloric acid shall be recalculated.

9.3 Sampling

The test sample shall be taken from accessible parts of individual toy and children product. The same material on a single product can be combined as the same test sample; but the material of other samples shall not be used at the same time. The test sample shall not contain more than one material or more than one color, unless the sample cannot be effectively separated by physical separation methods.

Example: physical separation methods which cannot be used for effective separation due to dot dyeing, printing textiles, or quality restrictions.

Note: it does not exclude the acquisition of any form of reference sample, as long as the reference sample can represent the relevant toy and children product material and the basic materials that are attached to them as specified above.

If the material mass is 10 mg ~ 100 mg, it shall be processed and calculated as 100 mg of test sample. The sample whose material mass is less than 10 mg can be exempted from testing.

9.4 Sample preparation

a coating on the to-be-tested material, firstly remove the coating on the material; then, perform sampling on the base material. The test sample shall be cut from the smallest thickness of the material section, so as to ensure that the ratio of the test sample area to the test sample mass is as large as possible.

9.5 Sample extraction

9.5.1 Glass, ceramic, metal materials

Put toy and children product or their components into a 50 mL glass container; the nominal size of the container is: height of 60 mm, diameter of 40 mm. Add simulated gastric juice (see 9.2) at room temperature, so that the solution can just immerse the test sample. Cover the container; protect it from light; place it at a temperature of (37 ± 2) °C for 2 h. Then, immediately separate the solids in the mixture effectively by filtration. If necessary, use a membrane filter (see 6.3) or a centrifuge (see 6.4) to separate. The centrifugation time shall not exceed 10 minutes, which shall be stated in the report.

9.5.2 Other materials

Use a suitable extraction container (see 6.6); mix the simulated gastric juice 50 times the mass of the test sample AND the test sample at room temperature. Shake for 1 min and check the acidity of the mixture. If the pH value is greater than 1.5, then, add dropwise hydrochloric acid solution (see 5.17) whose concentration is about 2 mol/L, until the pH value of the mixture reaches the range of 1.0 ~ 1.5. In a constant-temperature oscillator (see 6.5) at (37 ± 2) °C, avoid light; continue to oscillate for 1 h; then, leave it at (37 ± 2) °C for 1 h. Then, immediately separate the solids in the mixture effectively by filtration. If necessary, use a membrane filter (see 6.3) or a centrifuge (see 6.4) to separate. The centrifugation time shall not exceed 10 minutes, which shall be stated in the report. Immediately perform elemental analysis test of the filtrate.

For materials which contain grease, oils, waxes or similar materials, a dewaxing process shall be performed. Wrap the test sample in hard filter paper; before the extraction process, use n-heptane (see 5.14) or other suitable solvent extraction to remove the above components. Use appropriate analytical methods to ensure that the removal of these components is quantitative. The solvent that is used shall be stated in the report as required. After the wax is removed, leave the test sample on the hard filter paper; perform extraction of the hard filter paper and the test sample together. Use the original test sample mass to calculate the simulated gastric juice volume.

For paper, paperboard, and test samples that have been dewaxed, first add water (see 5.1) 25 times the mass of the test sample to soak the test sample; then, add hydrochloric acid solution (see 5.16), of which the mass is 25 times of the test sample and the concentration is 0.14 mol/L.

Appendix A

(Informative)

Selection guidance for migration test models

A.1 Overview

In order to use this Standard reasonably, it is necessary to understand the migration of certain elements in toy and children product in the body fluid environment. The way and degree of migration of certain elements to the human body are related to the way children use products and the characteristics of certain elements. The migration test models in this Appendix include sweat migration that is caused by contact of toy or children products with the skin, saliva migration that is caused by contact with the mouth, and gastric juice migration that is caused by swallowing. Related studies have confirmed that gastric juice migration capacity is often greater than sweat migration and saliva migration capacity.

A.2 Theoretical basis for sweat migration test model

Most toys and children products will have skin contact with users. For example, pencils and toys will intermittently or continuously come into contact with hands during use; children clothing will continue to come into contact with body skin during the wearing stage; children metal jewelry has been in prolonged contact with skin of specific parts of the body. Because human skin secretes sweat, the product material will be infiltrated to a certain extent when in contact with the skin, and certain elements in the material will be migrated out into the human sweat, and there is a potential risk of being absorbed by the body. Therefore, sweat migration is a common way that certain elements may enter the body.

A.3 Theoretical basis for saliva migration test model

Oral contact mainly includes actions such as sucking, licking, and chewing. Some children products on the market are specially designed for oral use, such as teething rings for children's bites, pacifiers for oral sucking. The products that are involved in oral behavior include a wide range; in addition to products which are specifically used for the mouth, it also includes other products that are easy to be bitten by children due to abuse, such as pens; although their size is too large to be completely put in the mouth, the raised part will still be bitten by children. In children's oral behavior, the product material will be infiltrated by saliva, and certain elements in the material will migrate out into the saliva of the human body, and there is a potential risk of being absorbed by the human body. Therefore, saliva migration is a common way that certain elements may enter the body.

a) Whether the children play mat be directly ingested? No, the infant play mat is large enough, and it is not a small part that can be ingested directly. It's unnecessary to consider branch 1.

b) Whether it can come into contact with the mouth? Yes, the corners of the play mat can come into contact with the mouth. It's necessary to consider branch 2. Whether it is easy to fall off due to biting when it comes into contact with the mouth? Yes, it is necessary to consider the gastric juice migration and the saliva migration.

c) Whether it can come into contact with the hands? Yes, the baby may crawl on the play mat and it is very likely to come into contact with the hands. It's necessary to consider branch 2. However, its materials are not easy to remain on the hands; it's necessary to consider sweat migration.

d) Whether it can come into contact with other parts of the body? Yes, infants may crawl or lie down on the play mat, and face, arms (which may be bare) and feet may be exposed; it's necessary to consider branch 4.

According to the evaluation results, there may be sweat migration, saliva migration, and gastric juice migration in the use of children floor mat.

Note that when using the migration test model evaluation figure, it is important to reasonably evaluate all possible occurrences of normal use and reasonable abuse of the product; do not miss any exposure patterns.

A.5.2 Examples of migration test model selection

A.5.2.1 Paperboard jigsaw puzzle for children under three

For the paperboard jigsaw toy product, it shall choose the gastric juice migration test model. According to the analysis in Figure A.1, toy products have three types of migration at the same time. Considering that the migration capacity of certain elements in gastric juice is often much greater than sweat migration and saliva migration, so, when a product has more than one exposure mode, and each exposure mode contributes equally, the gastric juice migration test model can be selected, that is, give priority to the most severe situation, so as to better protect children's health.

A.5.2.2 Infant textile and clothing products

For infant textile and clothing products, select the sweat migration test model. According to the analysis in Figure A.1, infant textile and clothing products have three types of migration at the same time; however, this product is a product that has been in contact with the skin for a long time, and the contribution of sweat migration is far greater than the contribution of gastric juice migration and saliva migration; so, select the sweat migration test model.

Appendix B

(Informative)

Selection guidance for test method (gravimetric method and area method)

B.1 Overview

Both the sweat migration test model and saliva migration test model in this Appendix provide two test methods, namely gravimetric method and area method.

B.2 Sweat migration test model

B.2.1 Overview

The sweat migration test model is mainly applicable to toys and children products mainly in contact with the skin, including but not limited to children clothing, children shoes, children accessories, children stationery, and children care products. Compared to gastric juice migration, children products which are involved in sweat migration tests usually have the characteristic of long-term contact with the skin.

B.2.2 Selection guidance for test method

The gravimetric method is generally suitable for toys and children products, which are mainly made of materials that are easily infiltrated by sweat, such as textile children products. In this case, it is difficult to calculate the effective contact area between the product material and sweat.

The area method is generally suitable for toys and children products, which are mainly made of materials that are not easily infiltrated by sweat, such as plastic children straps and metal children stationery boxes; therefore, the risk of migration of certain elements of surface materials to human sweat is greater; in this case, the area method is more consistent with the actual situation.

However, it is worth noting that if the materials of certain toys and children products are not easy to be infiltrated by sweat, but the materials are more likely to be worn away, so that the internal materials are exposed, the gravimetric method can also be considered. Because the same kind of toys and children products usually contain multiple materials, in this case, comprehensive consideration shall be given. In order to facilitate the operation of the test method, for all materials of the same kind of toys and children products, a relatively suitable migration test method can be used.

Appendix C

(Informative)

Technical information of migration test model

C.1 Overview

The determination of the technical conditions of the sweat, saliva, and gastric juice migration test models is based on the actual physiological conditions of children in China; it refers to the technical conditions of the existing standard system; at the same time, it comprehensively consider the requirements of migration conditions that are beneficial to most certain elements, and the protection of children health and safety.

C.2 Sweat migration test model

Human sweat mainly contains components, such as amino acids, lactic acid, ammonia, urea, inorganic salts; the skin surface pH is affected by various components, such as sebum that is secreted by the skin, emitted CO_2 and sweat. There is a certain difference in the sweat pH between children in the East and the West. For children in the East, the pH value of the skin surface of different body parts, different genders, and different age groups will have certain differences. The pH value of younger people is lower; the normal skin surface pH value of children in the East ranges at 4.4 ~ 5.6. The temperature of the human skin changes with the ambient temperature. When the human body sweats, the skin temperature is about 34 °C; the skin temperature after sweating no longer rises significantly.

C.3 Saliva migration test model

The main components of human saliva are water, electrolytes, sugars, lipids, proteins. With age, the components of saliva will change to some extent. The normal saliva pH of children in the East is about 7.0. The normal oral temperature of the human body is 36.9 °C ~ 37.5 °C.

Oral behavior is common in young children; younger children have longer daily oral behaviors and higher frequencies. Studies show that children's daily oral behavior time is different in different age groups; the maximum average length of each age group is about 2 h. The frequency of oral behavior of children under 24 months is about 81 times/h.

C.4 Gastric juice migration test model

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