

Note: the following is a provisional translation of an excerpt from the Ministerial Announcement No.370 of 1959, The specification and standards for food, food additives etc.

IV. Toys

A. Specifications for toys and their materials and components

1 Decal stickers must pass the test whose method is described below.

In this case, the water used in the test shall be distilled water.

(1) Preparation of test solution

Take colored area of the decal, take 2 ml of heated water of 40°C per 1cm² of surface area of it, soak sample in it and cover with a watch glass and maintaining its temperature at 40°C, leave it for 30 minutes with occasional stirring.

(2) Testing

1. Heavy Metals

When 20 ml of test solution is tested according to III: Part for Equipments, containers and packaging, B: Section for General testing methods for equipments, containers and packaging, 4: Paragraph for Heavy metals test, it must meet the specification thereof. When the specification is met, the amount of heavy metals in the test solution is no more than 1µg as lead/ml of test solution.

2. Arsenic

When 20 ml of test solution is tested according to Part III: Equipments, containers and packaging, Section B: General testing methods for equipments, containers and packaging, Paragraph 7: Arsenic test, it must meet the specification thereof. When the specification is met, the amount of arsenic in the form of arsenic trioxide in the test solution is no more than 0.1µg/ml of test solution.

2 Origami paper must pass the following test.

In this case, the water used in the test shall be distilled water.

(1) Preparation of test solution

Take 2 ml of preheated water of 40°C per 1cm² of surface area of it, soak sample in it and cover with a watch glass and maintaining its temperature at 40°C, leave it for 30 minutes with occasional stirring.

(2) Testing

1. Heavy Metals

Apply in the same way the prescription which is described in Part IV: Toys, Section A: Specifications for toys and their materials and components, Paragraph 1-(2): Testing, Sub-paragraph 1.: Heavy metals.

2. Arsenic

Apply in the same way the prescription which is described in Part IV: Toys, Section A: Specifications for toys and their materials and components, Paragraph 1-(2): Testing, Sub-paragraph 2.: Arsenic.

3 Rubber pacifiers must pass the test prescribed in Part III: Equipments, containers, and packaging, Section D: Material specific specification for equipments, containers, packaging, and their materials and components, Paragraph 3: Rubber equipments, containers, or packaging, Sub-paragraph 2: Testing methods for rubber bottle-feeding equipments.

4 Coating of toy must pass the following test.

(1) Preparation of test solution

Scraping the coating off the toy, comminute it to make it smaller than 0.5mm mesh, and use it as the sample. In case the coating is elastic, and unable to be comminuted, use as the sample the one which is minced as small as possible. Weigh more than 100mg of sample with precision, add 50 times volume of 0.07mol/l hydrochloric acid, and shake for one hour maintaining temperature at 37°C, with the shield from the light. Leave it still for one more hour at 37°C and filtrate. If the yield of the sample is more than 10mg and less than 100mg, add 5ml of 0.07mol/l hydrochloric acid and conduct testing. And if the yield of the sample is less than 10mg, the test is not conducted.

0.07mol/l hydrochloric acid; Add distilled water to 6.3ml of Hydrochloric acid, HCl, [K8180, Special grade], and make it 1,000ml.

(2) Testing

1. Cadmium, lead and arsenic

Take 0.1ml of cadmium standard undiluted solution, 0.1ml of lead standard undiluted solution and 1.3ml of arsenic standard undiluted solution, and add 0.07mol/l hydrochloric acid to make it 100ml. 1ml of this solution contains 1 μ g each of cadmium, lead and arsenic. Dilute this solution with 0.07mol/l hydrochloric acid, measure it with the same method as employed when measuring test solution, and draw carribration curve for each of cadmium, lead and arsenic. Use cadmium standard undiluted solution, lead standard undiluted solution and arsenic standard

undiluted solution prescribed in III, the Chapter for Equipments, containers and packages, C. Reagents, solutions etc., 4. Standard solutions, standard undiluted solutions. Determine the concentration of cadmium, lead and arsenic by atomic adsorption spectrometry or inductively coupled plasma atomic emission spectroscopy prescribed in III, the Chapter for Equipments, containers and packages, B. General test methods for equipments and containers and packages, 3. Atomic adsorption spectrometry and 9. Inductively coupled plasma atomic emission spectroscopy, and calculate the amount of migration per 1g of sample, using the following equation, and cadmium must be equal to or less than $75 \mu \text{ g/g}$, lead must be equal to or less than $90 \mu \text{ g/g}$ and arsenic must be equal to or less than $25 \mu \text{ g/g}$. When measure arsenic by atomic absorption, use the wave length of 193.7nm.

$$\text{Amount migrated}(\mu \text{ g/g}) = \frac{\text{Concentration in the sample solution } (\mu \text{ g/ml}) \times \text{volume of sample solution (ml)}}{\text{Amount of sample (g)}} \times \frac{100\text{-correction factor}}{100}$$

In this case, the correction factor for cadmium and lead is 30, correction factor for arsenic is 60.

5 Coating which contains poly vinyl chloride must pass the following test in addition to the test prescribed in IV, Chapter for Toy, A, Part for Specifications for toy and its materials, Item 4.

(1) Preparation of Sample Solution

Use a toy with coating or a piece isolated from it, as the sample, after dipping it into 2 ml of preheated water of 40°C per 1cm^2 of surface area of it, cover it with a watch glass, with maintaining its temperature at 40°C , leave it for 30 minutes with occasional stirring.

(2) Testing

1. Potassium permanganate consumption

When water is added to 50 ml of the sample solution to make it 100 ml and then testing is conducted on this according to III, Chapter for equipments, containers and packaging, B, Part for Testing methods for general equipments, containers and packaging, 1, Item for Testing method for potassium permanganate consumption, and calculate the amount of potassium permanganate consumption with the following formula, it must be equal to or less than $50 \mu\text{g/ml}$.

the amount of potassium permanganate consumption ($\mu \text{ g/ml}$) = $((a-b) \times 0.316 \times f \times 1,000) / 50$

Where

a: Titration volume (ml) of 0.002 mol/l potassium permanganate solution in sample test

b: Titration volume (ml) of 0.002 mol/l potassium permanganate solution in blank test

f: the factor for 0.002 mol/l potassium permanganate solution

2. Evaporation residue

When 200 – 300 ml of sample solution is used and testing is conducted according to III, Chapter of Equipments, containers and packaging, B, Part for General testing method for Equipments, containers and packaging, 5, Item for Evaporation residue test, then the amount must be equal to or less than 50µg/ml.

6 Parts which are made from poly vinyl chloride, not including the coatings, must pass the test described below. In this test, it is distilled water that is used.

(1) Preparation of Sample Solution

Use a toy or a piece isolated from it, as the sample, after dipping it into 2 ml of preheated water of 40°C per 1cm² of surface area of it, cover it with a watch glass, with maintaining its temperature at 40°C, leave it for 30 minutes with occasional stirring.

(2) Testing

1. Potassium permanganate consumption

Apply in the same way the prescription which is described in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 5, (2) Testing, 1. Potassium permanganate consumption.

2. Heavy Metals

Apply in the same way the prescription which is described in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 1, (2) Testing, 1. Heavy metals.

3. Cadmium

When five drops of nitric acid are added to 100 ml of the sample solution and cadmium testing is conducted according to III: Part for Equipments, containers and packaging, B: Part for Testing methods for general equipments, containers and packaging, 3: Atomic absorption spectrometry or 9: Inductively coupled plasma photoemission spectroscopy, it must comply with the standards thereof. In this test, take 10 ml of the cadmium control solution in III: Part for Equipments, containers and packaging, C: Section for Reagents and Solutions, add water to make 100 ml, add five drops of nitric acid and use this as the cadmium control solution. When it complies with this, the amount of cadmium in the sample solution is equal to or less

than 0.5µg/ml.

4. Evaporation residue

Apply in the same way the prescription which is described in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 5, (2) Testing, 2. Evaporation residue.

5. Arsenic

Apply in the same way the prescription which is described in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 1, (2) Testing, 2. Arsenic.

7 Synthetic resins whose major component is polyvinyl chloride made with bis (2-ethylhexyl) phthalate as material must not be used as material for toys.

8 Synthetic resins whose major component is polyvinyl chloride made with diisononyl phthalate as material must not be used as materials for toys prescribed in the Article 78-1 of the Enforcement Regulations of the Food Sanitation Law.

9 Parts which are made from polyethylene, not including the coatings, must pass the test described below. In this test, it is distilled water that is used.

(1) Preparation of Sample Solution

Use a toy or a piece isolated from it, as the sample, after dipping it into 2 ml of preheated water of 40°C per 1cm² of surface area of it, cover it with a watch glass, with maintaining its temperature at 40°C, leave it for 30 minutes with occasional stirring.

(2) Testing

1. Potassium permanganate consumption

When the testing is conducted according to the prescription in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 5, (2) Testing, 1. Potassium permanganate consumption, the amount must be equal to or less than 10 µ g/ml.

2. Heavy Metals

Apply in the same way the prescription which is described in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 1, (2) Testing, 1. Heavy metals.

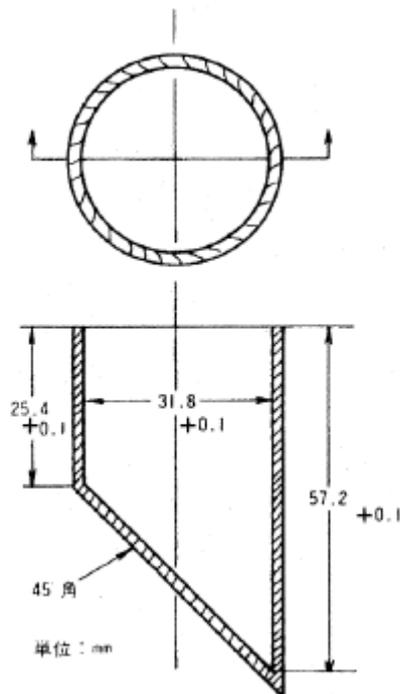
3. Evaporation residue

When the testing is conducted according to the prescription in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 5, (2) Testing, 2. Evaporation residue, the amount must be equal to or less than 30 µ g/ml.

4. Arsenic

Apply in the same way the prescription which is described in IV: Part for Toy, A: Section for Specifications for toys and their materials and components, 1, (2) Testing, 2. Arsenic.

10 Of metal jewelry toys, those with probability for infants or preschool children to swallow it must comply with the test described below. In this prescription, those with probability for infants or preschool children to swallow them are defined as those which are small enough to be contained, without compressing them, in the container with the size described in the following figure.



(1) Preparation of Sample Solution

Place the sample in the beaker with the diameter of approximately 40mm, add 37°C preheated 0.07mol/l hydrochloric acid until the sample sinks completely, leave it for 2 hours with the shield against light, and filtrate it.

0.07mol/l hydrochloric acid; Add distilled water to 6.3ml of hydrochloric acid, K8180 special grade, to make 1,000ml.

(2) Lead

Take 0.1ml of lead standard undiluted solution, add 0.07mol/l hydrochloric acid to

make 1,000ml. 1ml of this solution contains 1 μ g of lead. Dilute this solution with 0.07mol/l hydrochloric acid, measure lead in it in the same way as the sample solution, draw calibration line for lead. In this test, use ,as the lead standard solution, the solution prescribed in III: Part for Equipments, containers and packaging, C: Section for Reagents and Solutions, 4. Standard solutions, standard undiluted solutions.

When the concentration of lead is measured with the method in III: Part for Equipments, containers and packaging, B: Part for Testing methods for general equipments, containers and packaging, 3: Atomic absorption spectrometry or 9: Inductively coupled plasma photoemission spectroscopy, and calculate with the following formula the amount migrated per g of sample, the amount of lead leached must be equal to or less than 90 μ g/g.

$$\text{The amount leached (} \mu \text{ g/g)} = \frac{\text{Concentration in the sample solution (} \mu \text{ g/g)} \times \text{volume of sample solution (ml)}}{\text{Weight of sample (g)}} \times \frac{100 - \text{Correction factor}}{100}$$

In this calculation, the correction factor for lead is 30.

11 In case alternative method other than methods prescribed in 1 through 10 has precision equal to or more than methods prescribed, the alternative method may be employed. However, if there is any doubt on the result, final judgment must be made based upon the result obtained by the prescribed methods.

B Manufacturing standards of toy

1 When chemically synthesized coloring agents are used in the manufacturing of toys, no coloring agent other than those listed in the Attached table 1 of the Enforcement regulations of the Food Sanitation Law shall be used. However, this restriction does not apply to coloring agents that pass the following test.

After placing a colored piece of the sample in the 40°C preheated water, using 2 ml of water for each 1 cm² of surface area, cover it with a watch glass and leave it for 10 minutes with occasional stirring and maintain the temperature at 40°C, and use this as the sample solution. Place 50 ml of sample solution in a Nessler tube with inner diameter of 20 mm, and outer diameter of 24 mm, and 20 cm deep from its bottom to the bottom surface of the plug, and graduated every 5 ml up to 50 ml. When viewed from the top and the side, against a white background, no leach of the coloring agent should be recognized.