

## **Amendment to the Specifications and Standards for Foods, Food Additives, Etc.**

For calcium carbonate (a designated additive), the government of Japan will change the name of the substance, for which compositional specifications are already established, from calcium carbonate to calcium carbonate I, and will establish compositional specifications and use standards for calcium carbonate II.

### **Background**

Japan prohibits the sale of food additives that are not designated by the Minister of Health, Labour and Welfare (hereinafter referred to as “the Minister”) under Article 12 of the Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as “the Act”). In addition, when specifications or standards for food additives are stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370, 1959), Japan prohibits the sale of those additives unless they meet the specifications or the standards pursuant to Article 13 of the Act.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as “the Committee”) has discussed the adequacy of the revision of the specifications and the standards for calcium carbonate. The conclusion of the Committee is outlined below.

### **Outline of conclusion**

The Minister should change the substance name of calcium carbonate with compositional specifications to calcium carbonate I, and should establish compositional specifications and use standards for calcium carbonate II pursuant to Article 13 of the Act (see Attachment for the details).

## Attachment

# Calcium Carbonate II

炭酸カルシウム II

### Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

### Compositional Specifications (draft)

**Substance Name** Calcium Carbonate II

**Molecular Formula**  $\text{CaCO}_3$

**Molecular Weight** 100.09

**Chemical Name [CAS number]**

Calcium carbonate [471-34-1, Calcium carbonate]

**Definition** Calcium Carbonate II consists mainly of calcium carbonate. It is produced by a method through which the resulting product possibly contains the calcium double salt of L-tartaric and L-malic acids.

**Content** Calcium Carbonate II, when calculated on the dried basis, contains 98.0–102.0% of calcium carbonate ( $\text{CaCO}_3$ ).

**Description** Calcium Carbonate II occurs as a fine white powder. It is odorless.

**Identification** To 1 g of Calcium Carbonate II, add 10 mL of water and 7 mL of diluted acetic acid (1 in 4). It effervesces and dissolves. When boiled and neutralized with ammonia TS, this solution responds to all tests for Calcium Salt in the Qualitative Tests.

### **Purity**

(1) Hydrochloric acid-insoluble substances Not more than 0.20%.

Weigh 5.0 g of Calcium Carbonate II, add 10 mL of water, then gradually add 12 mL of hydrochloric acid dropwise while stirring, and add water to make 200 mL. Filter through a filter paper for quantitative analysis (5C), and wash the residue on the filter paper with boiling water until the washings are free of chloride. Heat gradually the residue together with the filter paper to carbonization, incinerate at 450–550°C for 3 hours or more, and weigh.

(2) Free alkali Weigh 3.0 g of Calcium Carbonate II, add 30 mL of freshly boiled and

cooled water, shake for 3 minutes, and filter the solution. To 20 mL of the filtrate, add 2 drops of phenolphthalein TS. A pink color develops, and it disappears when 0.20 mL of 0.1 mol/L hydrochloric acid is added.

(3) Lead Not more than 3 µg/g as Pb (2.0 g, Method 5, Control Solution: Lead Standard Solution 6.0 mL, Flame Method).

*Sample Solution* To the specified amount of Calcium Carbonate II, add 20 mL of diluted hydrochloric acid (1 in 4), and boil gently for 15 minutes with a watch glass covering it. Allow to cool, add 30 mL of water, and use the resulting solution as the sample solution. If the sample does not dissolve completely, evaporate it to dryness, and add 20 mL of diluted hydrochloric acid (1 in 4) to the residue. Boil gently for 5 minutes with a watch glass covering it, allow to cool, and add 30 mL of water.

In Method 5 of the Lead Limit Test, use 50 mL of a solution of diammonium hydrogen citrate (1 in 2) and 1 mL of bromothymol blue TS as the indicator instead of thymol blue TS, and then add ammonia solution until the color of the solution changes from yellow to yellow-green.

(4) Alkali metals and magnesium Not more than 1%.

Weigh 1.0 g of Calcium Carbonate II, dissolve it by gradually adding 30 mL of diluted hydrochloric acid (1 in 10), and let the carbon dioxide out by boiling. Cool, neutralize with ammonia TS, add 60 mL of a solution of ammonium oxalate monohydrate (1 in 25), and heat on a water bath for 1 hour. After cooling, add water to make 100 mL, and stir thoroughly. Centrifuge it, and filter the supernatant. Measure 50 mL of the filtrate, add 0.5 mL of sulfuric acid, evaporate to dryness, ignite to constant weight at 600°C, and weigh.

(5) Barium Not more than 0.030% as Ba.

*Test Solution* Weigh 1.0 g of Calcium Carbonate II, dissolve it in 8 mL of diluted hydrochloric acid (1 in 4), and add water to make 20 mL.

*Procedure* Add 2 g of sodium acetate trihydrate, 1 mL of diluted acetic acid (1 in 20), and 0.5 mL of potassium chromate solution (1 in 20) to the test solution, and allow to stand for 15 minutes. The solution is not more turbid than a control solution prepared as follows: To 0.30 mL of Barium Standard Solution, add water to make 20 mL, and then treat in the same manner as for the test solution.

(6) Arsenic Not more than 3 µg/g as As (0.50 g, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

*Test Solution* Weigh the specified amount of Calcium Carbonate II, moisten with 1 mL of water, and dissolve it in 4 mL of diluted hydrochloric acid (1 in 4).

**Loss on Drying** Not more than 2.0% (200°C, 4 hours).

**Assay** Weigh accurately about 2 g of Calcium Carbonate II, and add gradually exactly

50 mL of 1 mol/L hydrochloric acid. Heat the container containing the solution in a water bath for about 10 minutes. After cooling, titrate the excess hydrochloric acid with 1mol/L sodium hydroxide (indicator: 4–5 drops of methyl red TS). The endpoint is when red color of the solution changes to yellow. Calculate on the dried basis.

Each mL of 1 mol/L hydrochloric acid = 50.04 mg of  $\text{CaCO}_3$