

Amendment to the Ordinance for Enforcement of the Food Sanitation Act and the Specifications and Standards for Foods, Food Additives, Etc.

The government of Japan will designate Calcium L-tartrate as an authorized food additive and establish compositional specifications and standards for use of this additive.

Background

Japan prohibits the sale of food additives that are not designated by the Minister of Health, Labour and Welfare (“the Minister”) under Article 12 of the Food Sanitation Act (Act No. 233 of 1947; “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) pursuant to Article 13 of the Act, the sale of those additives are prohibited unless they meet the specifications or the standards.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of Calcium L-tartrate as a food additive. The conclusion of the committee is outlined below.

Outline of conclusion

The Minister should designate Calcium L-tartrate as a food additive unlikely to cause harm to human health pursuant to Article 12 of the Act and should establish compositional specifications and use standards for this additive pursuant to Article 13 of the Act (see Attachment for the details).

Attachment

Calcium L-Tartrate

L-酒石酸カルシウム

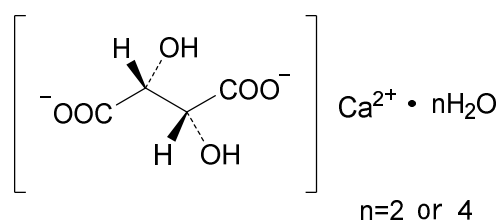
Standards for Use (draft)

Permitted for use only in grape wine. Must be used at not more than 2.0 g/L in grape wine as calcium L-tartrate.

Compositional Specifications (draft)

Substance Name Calcium L-Tartrate

Structural Formula



Molecular Formula $\text{C}_4\text{H}_4\text{CaO}_6 \cdot n\text{H}_2\text{O}$ (n= 2 or 4)

Molecular Weight Dihydrate 224.18
Tetrahydrate 260.21

Chemical Name [CAS number]

Calcium(2*R*, 3*R*)-2,3-dihydroxybutanedioate dihydrate

Calcium(2*R*, 3*R*)-2,3-dihydroxybutanedioate tetrahydrate [5892-21-7]

Content Calcium L-Tartrate, when dried, contains not less than 98.0% of calcium L-tartrate ($\text{C}_4\text{H}_4\text{CaO}_6$).

Description Calcium L-Tartrate occurs as a white to grayish white powder.

Identification

(1) Dissolve 1 g of Calcium L-Tartrate by adding hydrochloric acid TS (1 mol/L) to make 50 mL. This solution is dextrorotatory.

(2) Calcium L-Tartrate responds to test (1) for Calcium Salt in the Qualitative Tests.

(3) A solution of 1 g of Calcium L-Tartrate in 50 mL of hydrochloric acid TS (1 mol/L) responds to test (3) for Tartrate in the Qualitative Tests.

Specific Rotation $[\alpha]_D^{20}$: +6.2 to +7.4°.

Weigh accurately about 1 g of Calcium L-Tartrate, and dissolve it by adding hydrochloric acid TS (1 mol/L) to make exactly 50 mL. Measure the optical rotation of this solution.

pH 6.0–9.5.

Test Solution To 3.0 g of Calcium L-Tartrate, add 60 mL of water, shake it for 1 hour, and centrifuge for 5 minutes at 3000 rpm. Use the supernatant.

Purity

(1) **Lead** Not more than 5 µg/g as Pb (0.80 g, Method 3, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

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

Test Solution Dissolve the specified amount of Calcium L-Tartrate by adding 5 mL of diluted hydrochloric acid (1 in 4).

(3) **Sulfate** Not more than 0.1% as SO₄.

Test Solution Dissolve 1.2 g of Calcium L-Tartrate by adding 30 mL of hydrochloric acid TS (1 mol/L), and further add hydrochloric acid TS (1 mol/L) to make 50 mL.

Control Solution To 2.5 mL of 0.005 mol/L sulfuric acid, add hydrochloric acid TS (1 mol/L) to make 50 mL.

(4) **Basic residues** Not more than 3% as CaCO₃.

Weigh accurately about 2 g of Calcium L-Tartrate in a container, add gradually exactly measured 25 mL of 1 mol/L hydrochloric acid, and heat the container with the solution in a water bath for about 10 minutes. After cooling, titrate the excess hydrochloric acid with 1 mol/L sodium hydroxide (indicator: 4–5 drops of methyl red TS). The endpoint is when the color of the solution changes from red to yellow. Separately, perform a blank test, and determine the amount of basic residues by the formula:

$$\text{The amount of basic residues (CaCO}_3\text{)} = \frac{(a - b) \times 5.004}{\text{weight (g) of the sample}}$$

a = volume (mL) of 1 mol/L sodium hydroxide consumed in the blank test,

b = volume (mL) of 1 mol/L sodium hydroxide consumed in the test.

Loss on Drying Not more than 30.0% (200°C, 7 hours).

Assay

Test Solution Weigh accurately about 1 g of Calcium L-Tartrate, mix it with 8 mL of diluted hydrochloric acid (1 in 4), and dissolve by adding about 20 mL of water. Warm if necessary to dissolve it, and cool to room temperature. To this solution, further add water to make exactly 50 mL.

Procedure Quantify calcium L-tartrate in the sample by Method 1 of Calcium Salt Determination. Calculate the content on dried basis.

Each mL of 0.05 mol/L of disodium dihydrogen ethylenediaminetetraacetate = 9.407 mg of C₄H₄CaO₆