

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 dipotassium L-tartrate as an authorized food additive and establish compositional specifications and use standards for this additive.

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 designation of dipotassium L-tartrate as a food additive. The conclusion of the Committee is outlined below.

Outline of conclusion

The Minister should designate dipotassium 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

Dipotassium L-Tartrate

L-酒石酸カリウム

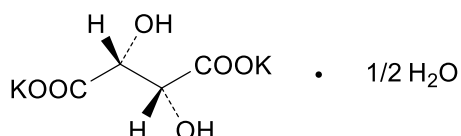
Standards for Use (draft)

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

Compositional Specifications (draft)

Substance Name Dipotassium L-Tartrate

Structural Formula



Molecular Formula $\text{C}_4\text{H}_4\text{K}_2\text{O}_6 \cdot \frac{1}{2}\text{H}_2\text{O}$

Molecular Weight 235.28

Chemical Name [CAS number]

Dipotassium (2*R*,3*R*)-2,3-dihydroxybutanedioate hemihydrate [6100-19-2]

Content Dipotassium L-Tartrate, when dried, contains not less than 99.0% of dipotassium L-tartrate ($\text{C}_4\text{H}_4\text{K}_2\text{O}_6 = 226.27$).

Description Dipotassium L-Tartrate occurs as colorless to white crystals or fine granular powder.

Identification

- (1) A solution of Dipotassium L-Tartrate (1 in 10) is dextrorotatory.
- (2) Dipotassium L-Tartrate responds to test (1) for Calcium Salt and to all tests for Tartrate in the Qualitative Tests.

Specific Rotation $[\alpha]_{\text{D}}^{20}$: +27.2 to +29.7° (5 g, water, 50 mL, on the dried basis).

pH 7.0–9.0 (0.5 g, water 50 mL).

Purity

(1) Lead Not more than 2 µg/g as Pb (2.0 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, Method 1, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

(3) Oxalate Not more than 100 µg/g as C₂H₂O₄.

Test Solution Weigh 0.100 g of Dipotassium L-Tartrate, previously dried, and add sulfuric acid TS (0.01 mol/L) to dissolve it and to make exactly 20 mL.

Control Solution Weigh 140 mg of oxalic acid dihydrate, and add sulfuric acid TS (0.01 mol/L) to dissolve it and to make exactly 1000 mL. To exactly 1 mL of this solution, add sulfuric acid TS (0.01 mol/L) to make exactly 200 mL.

Procedure Analyze 10-µL portions of the test solution and the control solution by liquid chromatography using the operating conditions given below. Measure the peak area of oxalic acid for each of the test and control solutions by the automatic integration method. The peak area of oxalic acid for the test solution is not larger than that for the control solution.

Operating Conditions

Detector: Ultraviolet spectrophotometer (wavelength: 210 nm).

Column: A stainless steel tube (6–8 mm internal diameter and 30 cm length). If necessary, two connected columns may be used.

Column packing material: 8-µm H-form cation-exchange resin for liquid chromatography.

Guard column: Use a column with the same internal diameter that is packed with the same packing material as for the column above.

Column temperature: 50°C.

Eluent: Sulfuric acid TS (0.01 mol/L).

Flow rate: 0.6 mL/min.

Loss on Drying Not more than 4.0% (150°C, 4 hours).

Assay Weigh accurately about 0.2 g of Dipotassium L-Tartrate, previously dried, add 3 mL of formic acid, and dissolve it by warming. Add 50 mL of acetic acid for nonaqueous titration, and titrate with 0.1 mol/L perchloric acid. Usually, a potentiometer is used to confirm the endpoint. When crystal violet–acetic acid TS (1 mL) is used as the indicator, the endpoint is when the color of the solution changes from purple through blue to green. Separately, perform a blank test to make any necessary correction.

Each mL of 0.1 mol/L perchloric acid = 11.31 mg of C₄H₄K₂O₆

Reagents, Solutions, and Other Reference Materials

Sulfuric Acid TS (0.01 mol/L) Add water to 10 mL of sulfuric acid TS (1 mol/L) to make 1000 mL.