

Amendment to the Enforcement Ordinance of the Food Sanitation Law and the Standards and Specifications for Foods and Food Additives

The government of Japan will designate Sodium Selenite as an authorized food additive.

Summary

Under Article 10 of the Food Sanitation Law (hereinafter referred to as the “Law”), food additives shall not be used or marketed without authorization by the Minister of Health, Labour and Welfare (hereinafter referred to as “the Minister”). In addition, when specifications or standards are established for food additives based on Article 11 of the Law and stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or marketed unless they meet the standards or specifications.

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

Outline of conclusion

The Minister, based on Article 10 of the Law, should designate Sodium Selenite, as a food additive unlikely to harm human health, and establish standards for use and compositional specifications, based on Article 11 of the Law (see Attachment).

Attachment

Sodium Selenite

亜セレン酸ナトリウム

Standards for use

Sodium Selenite is permitted only in powdered formulated breast milk substitutes [(cow's milk-based powdered formulated milk (infant formula and follow-up formula) and other breast milk substitutes*].

When used in other breast milk substitutes, it shall not be contained at a level exceeding 5.5 µg as Se per 100 kcal for each product.

*Other breast milk substitutes include non-milk based formula, such as soy milk

Compositional specifications

Substance name Sodium Selenite

Molecular formula $\text{Na}_2\text{SeO}_3 \cdot 5\text{H}_2\text{O}$

Molecular weight 263.01

Chemical name [CAS number]

Disodium Selenite Pentahydrate [26970-82-1]

Content Sodium Selenite contains 98.5–101.5% of sodium selenite ($\text{Na}_2\text{SeO}_3 \cdot 5\text{H}_2\text{O}$).

Description Sodium Selenite occurs as a white crystalline powder.

Identification

(1) Dissolve 0.05 g of Sodium Selenite by adding 2.5 ml of water and 2.5 ml of dilute hydrochloric acid, and boil. When 0.05 g of L-ascorbic acid is added, the resulting solution produces a red precipitate. When left to stand for a few minutes, the color of the precipitate changes to red-brown to black.

(2) Dissolve 0.05 g of Sodium Selenite by adding 5 ml of water and 1 ml of dilute hydrochloric acid. When 1 ml of barium chloride solution (3 in 50) is added, no precipitate is produced.

(3) Sodium selenite responds to all tests for Sodium Salt in the Qualitative Tests.

Purity

(1) Clarity of solution Colorless and clear (2.0 g, carbon dioxide-free water 20 ml).

(2) pH 9.8–10.8 (2.0 g, carbon dioxide-free water 20 ml).

(3) Chloride Not more than 0.005% as Cl.

Sample Solution Place 2.0 g of sodium selenite into a Nessler tube, and dissolve it by adding about 30 ml of water. Add 4 ml of nitric acid and mix.

Control Solution Use 0.30 ml of 0.01 mol/L hydrochloric acid.

(4) Sulfate Not more than 0.03% as SO₄ (0.8 g, Control solution: 0.005 mol/L sulfuric acid 0.50 ml).

(5) Lead Not more than 2.0 µg/g as Pb.

Standard Solution Measure exactly 2 ml of Lead Standard Stock Solution into a 100-ml volumetric flask, and add nitric acid (1 in 200) to volume.

Test Solution Weigh 1.00 g of sodium selenite into a 10-ml volumetric flask, dissolve it by adding nitric acid (1 in 200) to make 10 ml.

Standard Test Solutions Weigh 1.00 g of sodium selenite into each of three 10-ml volumetric flasks. To the flasks, add 0.5 ml, 1 ml, and 2 ml of the standard solution separately, and dissolve them by adding nitric acid (1 in 200) to make 10 ml of each solution.

Procedure Determine the emission intensity of lead in the test solution and standard test solutions by inductive coupled plasma-atomic emission spectrometry. Plot the values obtained on a graph, with the amount (µg) in each solution on the x axis and emission intensity on the y axis, to prepare regression lines for the three elements. Determine the amount of lead in the sample from the distance between the origin and the intersection of the regression line and the x axis.

(6) Iron Not more than 50 µg/g as Fe.

Standard Solution Measure exactly 5 ml of Iron Standard Stock Solution) into a 100-ml volumetric flask, and add nitric acid (1 in 200) to volume.

Test Solution Weigh 1.00 g of sodium selenite into a 10-ml volumetric flask, dissolve it by adding nitric acid (1 in 200) to make 10 ml.

Standard Test Solutions Weigh 1.00 g of sodium selenite into each of three 10-ml volumetric flasks. To the flasks, add 0.5 ml, 1 ml, and 2 ml of the standard solution separately, and dissolve them by adding nitric acid (1 in 200) to make 10 ml of each solution.

Procedure Determine the emission intensity of iron in the test solution and standard test solutions by inductive coupled plasma-atomic emission spectrometry. Plot the values obtained on a graph, with the amount (µg) in each solution on the x axis and emission intensity on the y axis, to prepare regression lines for the three elements. Determine the amount of iron in the sample from the distance between the origin and the intersection of the regression line and the x axis.

(7) Arsenic Not more than 4.0 µg/g as As₂O₃.

Standard Solution Measure exactly 3 ml of Arsenic Standard Stock Solution (for inductive coupled plasma-atomic emission spectrometry) into a 100-ml volumetric flask, and add nitric acid (1 in 200) to volume.

Test Solution Weigh 1.00 g of sodium selenite into a 10-ml volumetric flask, dissolve it by adding nitric acid (1 in 200) to make 10 ml.

Standard Test Solutions Weigh 1.00 g of sodium selenite into each of three 10-ml volumetric flasks. To the flasks, add 0.5 ml, 1 ml, and 2 ml of the standard solution separately, and dissolve them by adding nitric acid (1 in 200) to make 10 ml of each solution.

Procedure Determine the emission intensity of arsenic in the test solution and standard test solutions by inductive coupled plasma-atomic emission spectrometry. Plot the values obtained on a graph, with the amount (µg) in each solution on the x axis and emission intensity on the y axis, to prepare regression lines for the three elements. Determine the amount of arsenic in the sample from the distance between the origin and the intersection of the regression line and the x axis.

Assay Weigh accurately about 0.1 g of sodium selenite into a stoppered flask, and dissolve it by adding 100 ml of water. To this solution, add 3 g of potassium iodide and 5 ml of diluted hydrochloric acid (2 in 3), immediately stopper tightly, and allow to stand in a dark place for 5 minutes. Titrate the liberated iodine with 0.1 mol/L sodium thiosulfate (indicator: 3 ml of starch TS). Add starch TS near the endpoint of the titration, when the solution is pale yellow-red. The endpoint is when the blue color produced disappears. Separately perform a blank test to make a correction.

Each ml of 0.1 mol/L sodium thiosulfate = 6.575 mg of Na₂SeO₃·5H₂O

Reagents and Test Solutions (TS)

Arsenic Standard Stock Solution (for inductive coupled plasma-atomic emission spectrometry) Weigh exactly 0.10 g of arsenic trioxide, previously powdered finely and dried for 4 hours at 105°C, dissolve it by adding 6 ml of sodium hydroxide solution (1 in 10), and add 500 ml of water. Adjust the pH to 3 to 5 with diluted hydrochloric acid (1 in 4), and add water to make exactly 1000 ml. Each ml of this solution contains 0.1 mg of arsenic trioxide (As₂O₃).

Iron Standard Stock Solution Weigh exactly 8.63 g of ammonium iron(III) sulfate

dodecahydrate, dissolve it by adding 25 ml of diluted nitric acid (1 in 3) and water, and add water to this solution to make exactly 1000 ml. Each ml of this solution contains 1 mg of iron (Fe). Store, protected from light.