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 Hypobromous acid water 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 Hypobromous acid water 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 Hypobromous acid water, 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

Hypobromous Acid Water

次亜臭素酸水

Standard for use

Hypobromous Acid Water is permitted only for the surface disinfection of edible meat. The maximum use level (as the amount of bromine in 1 kg of a dipping or spray solution) is 0.90 g for edible meat (excluding poultry) and 0.45 g for poultry.

Compositional specifications

Substance name Hypobromous acid water

Definition Hypobromous Acid Water is an aqueous solution consisting mainly of hypobromous acid. It is obtained by hydrolyzing 1,3-dibromo-5,5-dimethylhydantoin.

Content Hypobromous Acid Water contains 75–900 mg/kg of available bromine.

Description Hypobromous Acid Water is a colorless liquid. It is odorless or has a slight characteristic odor.

Identification

(1) To 10 ml of Hypobromous Acid Water, add 0.15 g of potassium iodide. A yellow to brown color is produced.

(2) Prepare a test solution by adding 1 ml of Hypobromous Acid Water to 89 ml of water. To 0.5 ml of DPD–EDTA TS, add 0.5 ml of phosphate buffer (containing disodium ethylenediaminetetraacetate) and 10 ml of the test solution. A light red color is produced.

(3) The solution obtained by adding 1 drop of sodium hydroxide solution (1 in 2) to 10 ml of Hypobromous Acid Water exhibits an absorption maximum at a wavelength of 324–330 nm.

Purity

pH 4.0–7.5.

Assay Weigh accurately about 20 g of Hypobromous Acid Water, add 50 ml of water, and then add 1 g of potassium iodide and 5 ml of diluted acetic acid (1 in 4). Immediately stopper tightly and allow to stand in a dark place for 15 minutes. Titrate the liberated iodine with 0.01 mol/L sodium thiosulfate (indicator: 3 ml of starch TS).

Add starch TS near the endpoint, when the solution is pale yellow. The endpoint is when the blue color produced disappears. Separately, perform a blank test to make any necessary correction.

Each ml of 0.01 mol/L sodium thiosulfate = 0.7990 mg of Br

Regents and Solutions ***N,N*-Diethyl-*p*-phenylenediamine Sulfate** $(C_2H_5)_2NC_6H_4NH_2 \cdot H_2SO_4$ A white to slightly pale brown granules, or powder. Soluble in water.

Content Contains not less than 98.0% of *N,N*-diethyl-*p*-phenylenediamine sulfate ($(C_2H_5)_2NC_6H_4NH_2 \cdot H_2SO_4$).

Identification 5 ml of a 1 in 40 solution of *N,N*-Diethyl-*p*-phenylenediamine Sulfate produces a white precipitate when 1 ml of barium chloride solution (1 in 10) is added.

Purity (1) Clarity of solution Almost clear (0.5 g, water 20 ml).

(2) Absorbance Weigh exactly 0.02 g of *N,N*-Diethyl-*p*-phenylenediamine Sulfate, add 2.5 ml of phosphate buffer (pH 6.5, containing 1,2-cyclohexanediaminetetraacetic acid) and 0.48 g of sodium sulfate, dissolve the solids, and dilute to exactly 50 ml with water. Refer to this solution as Solution A. Measure the absorbance of the solution against water by ultraviolet-visible spectrophotometry. It is not more than 0.005 at a wavelength of 555 nm. Then, prepare a solution obtained by dissolving 0.3 g of potassium iodide in 30 ml of Solution A and leaving for 2 minutes and measure its absorbance against water in the same manner. It is not more than 0.005 at a wavelength of 555 nm. Separately, perform a blank test for each solution to make any necessary correction.

Assay Weigh accurately about 0.2 g of *N,N*-Diethyl-*p*-phenylenediamine Sulfate and dissolve it in 50 ml of water. Titrate the solution with 0.1 mol/L sodium hydroxide. Use a potentiometer to confirm the endpoint. The endpoint is when the titration curve shows a second inflection point. Make correction with the volume of titration consumed by the first inflection point.

Each ml of 0.1 mol/L sodium hydroxide = 26.23 mg of $(C_2H_5)_2NC_6H_4NH_2 \cdot H_2SO_4$

1,2-Cyclohexanediaminetetraacetic Acid Monohydrate $C_{14}H_{22}N_2O_8 \cdot H_2O$ A white powder.

Content Contains not less than 99.0% of *trans*-1,2-cyclohexanediaminetetraacetic acid monohydrate ($C_{14}H_{22}N_2O_8 \cdot H_2O$).

Identification Determine the absorption spectrum of 1,2-Cyclohexanediaminetetraacetic Acid Monohydrate as directed in the Potassium

Bromide Disk Method under Infrared Spectrometry. The spectrum exhibits absorption at about 3000 cm^{-1}, 1750 cm^{-1}, 1710 cm^{-1}, 1590 cm^{-1}, 1430 cm^{-1}, 1400 cm^{-1}, 1240 cm^{-1}, and 1220cm^{-1}.

Purity Clarity of solution Almost clear. Prepare a test solution by dissolving 4.0 g of 1,2-Cyclohexanediaminetetraacetic Acid Monohydrate in 25 ml of sodium hydroxide TS and diluting the solution to 100 ml with water.

Assay Weigh accurately 0.4 g of 1,2-Cyclohexanediaminetetraacetic Acid Monohydrate, and dissolve it in 11 ml of sodium hydroxide. Add 2 ml of ammonia–ammonium chloride buffer (pH 10.7) and water to make 100 ml. Titrate the resulting solution with 0.05 mol/L zinc chloride (indicator: 5 drops of eriochrome black TS).

Each ml of 0.05 mol/L zinc chloride = 18.22 mg of $C_{14}H_{22}N_2O_8 \cdot H_2O$

DPD–EDTA TS Pulverize 1.1 g of *N,N*-diethyl-*p*-phenylenediamine sulfate in an agate mortar. Add 0.2 g of disodium ethylenediaminetetraacetate dihydrate and a small amount of water to dissolve them if necessary by heating with stirring. Add 8 ml of 25% (w/v) of diluted sulfuric acid, and mix. Dilute the resulting solution to 1000 ml with water.

Phosphate Buffer (containing disodium ethylenediaminetetraacetate) Dissolve 24.0 g of anhydrous disodium potassium, 46.0 g of monopotassium phosphate, and 0.8 g of disodium ethylenediaminetetraacetate dihydrate in water to make 1000 ml.

Phosphate Buffer (pH6.5, containing 1,2-cyclohexanediaminetetraacetic acid) Dissolve 2.7 g of monopotassium phosphate in water to make exactly 100 ml. Adjust the pH to 6.5 with 0.2 mol/L sodium hydroxide. Dissolve 0.13 g of 1,2-cyclohexanediaminetetraacetic acid in the resulting solution.