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Designation and Revision of Two Food Additives

2007

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Report Highlights:

On November 7, 2007, Japan proposed the designation of Magnesium Hydroxide as a Food Additive and Revision of Compositional Specifications for Hypochlorous Acid Water. Japan will notify these changes to the WTO SPS Committee.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Tokyo [JA1]
[JA]

Executive Summary

On November 7, 2007, the Ministry of Health, Labor, and Welfare (MHLW) proposed the designation of Magnesium Hydroxide as a Food Additive and revision of the compositional specifications for the previously designated additive Hypochlorous Acid Water. MHLW's public comment period closed November 21, 2007. However, MHLW intends to notify these changes to the WTO/SPS Committee, which would be the last chance for public comments to be submitted on this subject. After the WTO comment period closes, the Pharmaceutical Affairs and Food Sanitation Council will meet and the conclusions of the session will then be submitted in a report to MHLW, constituting the final decision.

If you have comments you would like to be considered for inclusion in the official U.S. Government comments to MHLW, please send them to the Agricultural Affairs Office of the U.S. Embassy in Tokyo at agtokyo@usda.gov.

Comments can also be sent directly to MHLW at:

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Designation of Magnesium Hydroxide as a Food Additive and Revision of Compositional Specifications for Hypochlorous Acid Water

Purpose

This activity is to newly designate magnesium hydroxide as an authorized food additive and to partially revise compositional specifications for hypochlorous acid water.

Under Article 10 of the Food Sanitation Law, food additives can be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. When use standards or compositional specifications are established for food additives, based on Article 11 of the law, those additives are not permitted to be marketed unless they meet these standards or specifications.

In response to a request from the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of the substance and the revision of the existing specifications. The subcommittee has concluded as follows.

Outline

The Minister should designate magnesium hydroxide, based on Article 10 of the Food Sanitation Law, as a food additive unlikely to harm human health and establish compositional specifications for the substance, based on Article 11 of the law (see Attachment 2-1). Also, the Minister should revise the compositional specifications of hypochlorous acid water based, based on Article 11 (see Attachment 2-2).

Additional Information

Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 2-3)

Magnesium Hydroxide

Standard for use

No standards will be established.

Compositional specifications

Substance name Magnesium hydroxide

Molecular formula $\text{Mg}(\text{OH})_2$

Mol. Weight. 58.32

Chemical name, CAS number Magnesium hydroxide [1309-42-8]

Content Not less than 95.0% of magnesium hydroxide ($\text{Mg}(\text{OH})_2$), when dried.

Description Occurs as an odorless, white powder.

Identification (1) To 0.1 g of Magnesium Hydroxide, add 10 ml of water, and shake. The resulting liquid is alkaline.

(2) A solution of 1 g of Magnesium Hydroxide in 20 ml of dilute hydrochloric acid responds to the test for Magnesium Salt as directed in the Qualitative Tests.

Purity (1) Free alkali and soluble salts Weigh 2.0 g of Magnesium Hydroxide into a beaker, and add 100 ml of water. Cover the beaker with a watch dish, and heat it in a water bath for 5 minutes. Immediately filter the mixture, and cool. To 50 ml of the filtrate, add 2 drops of methyl red TS, and titrate with 0.05 mol/L sulfuric acid. The volume of the sulfuric acid consumed is not more than 2.0 ml. Evaporate 25 ml of the filtrate, measured exactly, to dryness, and dry the residue at 105°C for 3 hours. The mass of the residue is not more than 0.010 g.

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

Test Solution Weigh 5.0 g of Magnesium Hydroxide into a 200-ml beaker, dissolve it in 40 ml of diluted hydrochloric acid (12 in 25), cover the beaker with a watch dish, and boil for 5 minutes. Cool, and add 10 ml of diammonium hydrogen citrate solution (1 in 2), and make weakly alkaline with aqueous ammonia, using thymol blue TS as the indicator. Cool, transfer it to a 200-ml separating funnel, wash the beaker with water, collect the washings into the funnel, and make about 100 ml. Add 5 ml of ammonium pyrrolidine dithiocarbamate solution (3 in 100), allow to stand for 5 minutes, add 10 ml of butyl acetate, shake for 5 minutes, and allow to stand. Use the butyl acetate layer as the test solution.

Control Solution Add water to 1 ml of Lead Standard Stock Solution, measured exactly, to make 100 ml. Measure exactly 10 ml of the resulting solution, and proceed in the same manner as for the test solution.

Procedure With the test solution and control solution, proceed as directed under Method 1 in the Lead Limit Test.

(3) Calcium oxide Not more than 1.5%.

Weigh accurately about 0.35 g of Magnesium Hydroxide, add 6 ml of dilute hydrochloric acid, and dissolve by warming. Cool, and add 300 ml of water, 3 ml of tartaric acid solution (1 in 5), 10 ml of 2,2',2''-nitrilotriethanol solution (3 in 10), and 10 ml of potassium hydroxide (1 in 2), and allow to stand for 5 minutes. Titrate with 0.01 mol/L EDTA (indicator: about 0.1 g of NN indicator). The endpoint is when the solution turns from red-violet to blue. Perform a blank test to make necessary correction, and obtain the content of calcium oxide.

1 ml of 0.01 mol/L EDTA = 0.5608 mg of CaO

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

Test Solution Dissolve 0.50 g of Magnesium Hydroxide in 8 ml of dilute hydrochloric acid.

Apparatus Use Apparatus B.

Loss on Drying Not more than 2.0% (105°C, 2 hours)

Loss on Ignition 30.0–33.0% (800°C, constant weight).

Assay Weigh accurately about 0.3 g of Magnesium Hydroxide, previously dried, add 10 ml of water and 4.0 ml of dilute hydrochloric acid, and dissolve with warming. Cool, and add water to make exact 100 ml. To 25 ml of the resulting solution, measured exactly, add 50 ml of water and 5 ml of ammonia–ammonium chloride buffer (pH 10.7), and titrate with 0.05 mol/L EDTA (indicator: 0.04 g of eriochrome black T–sodium chloride indicator). Perform a blank test. Obtain the content by the following formula, using the content of CaO obtained in Purity (3).

$$\text{Content (\% of magnesium hydroxide (Mg(OH)}_2\text{))} = \frac{(a - b - c \times \text{weight (g) of the sample} \times 0.9) \times 1.1664}{\text{Weight (g) of the sample}}$$

Where a = Volume (ml) of 0.05 mol/L EDTA consumed by the test solution,

b = Volume (ml) of 0.05 mol/L EDTA consumed by the blank,

c = Content(%) of calcium oxide (CaO) obtained in Purity (3).

Regents

Diammonium Hydrogen Citrate C₆H₁₄N₂O₇ K8284

Butyl Acetate CH₃COOCH₂CH₂CH₂CH₃ K8377

Hypochlorous Acid Water

Definition Hypochlorous Acid Water is an aqueous solution consisting mainly of hypochlorous acid. It is obtained by electrolyzing hydrochloric acid or a ~~saline~~ solution of sodium chloride. There are ~~two~~ three types of solutions: Strongly Acidic Hypochlorous Acid Water, Weakly Acidic Hypochlorous Acid Water, and Slightly Acidic Hypochlorous Acid Water.

Strongly Acidic Hypochlorous Acid Water : A solution produced from the anode side by electrolyzing sodium chloride solution of not more than 0.2% in an electrolytic cell with a septum (“electrolytic cell with a septum” refers to a cell consisting of an anode and a cathode separated by a septum).

Weakly Acidic Hypochlorous Acid Water: A solution produced from the anode side by electrolyzing sodium chloride solution with an appropriate concentration in an electrolytic cell with a septum (“electrolytic cell with a septum” refers to a cell consisting of an anode and a cathode separated by a septum), or a solution produced by adding an aqueous solution obtained from the cathode side to an aqueous solution obtained from the anode side.

Slightly Acidic Hypochlorous Acid Water: A solution produced from the cathode side by electrolyzing ~~2–6%~~ an aquatic solution of hydrochloric acid with appropriate concentration or an aquatic solution of hydrochloric acid with appropriate concentration to which sodium chloride is added if necessary in an electrolytic cell without a septum (“electrolytic cell without a septum” refers to a cell consisting of an anode and a cathode not separated by a septum).

Content Strongly Acidic Hypochlorous Acid Water contains 20–60 mg/kg of available chlorine.

Weakly Acidic Hypochlorous Acid Water contains 10–60 mg/kg of available chlorine.

Slightly Acidic Hypochlorous Acid Water contains 10–~~30~~80 mg/kg of available chlorine.

Description Hypochlorous Acid Water is a colorless liquid. It has little or no odor of chlorine.

Identification (1) To 5 ml of Hypochlorous Acid Water, add 1 ml of a sodium hydroxide solution (1 in 2,500) and 0.2 ml of potassium iodide TS. A yellow color is produced. To the resulting solution, add 0.5 ml of starch TS. The solution turns deep blue.

(2) To 5 ml of Hypochlorous Acid Water, add 0.1 ml of a potassium permanganate solution (1 in 300), and then add 1 ml of diluted sulfuric acid (1 in 20). A reddish purple color of the solution does not fade.

(3) A solution of 90 ml of Hypochlorous Acid Water in 10 ml of sodium hydroxide

solution (1 in 5) exhibits an absorption maximum at a wavelength of 290–294 nm.

Purity (1) pH Strongly Acidic Hypochlorous Acid Water: Not more than 2.7.

Weakly Acidic Hypochlorous Acid Water: 2.7–5.0.

Slightly Acidic Hypochlorous Acid Water: 5.0–6.5.

(2) Residue on drying (evaporating) Not more than 0.25 %.

Weigh and evaporate 20.0 g of Hypochlorous Acid Water. Then dry it at 110 °C for 2 hours, and weigh the residue.

Assay ~~(1) Strongly Acidic Hypochlorous Acid Water~~ Weigh accurately about 200 g of Hypochlorous Acid Water, add 2 g of potassium iodide and 10 ml of diluted acetic acid (1 in 4), immediately stopper the container, and allow to stand in a dark place for 15 minutes. Titrate the liberated iodine with 0.01 mol/L sodium thiosulfate, using starch TS as the indicator. Separately, perform a blank test in the same manner to make any necessary correction.

1 ml of 0.01 mol/L sodium thiosulfate = 0.35453 mg Cl

~~(2) Slightly Acidic Hypochlorous Acid Water~~ Weigh accurately about 200 g of Hypochlorous Acid Water, add 2 g of potassium iodide and 10 ml of diluted acetic acid (1 in 4), quickly stopper the container, and allow to stand in a dark place for 15 minutes. Titrate the liberated iodine with 0.005 mol/L sodium thiosulfate, using starch TS as an indicator. Separately, perform a blank test in the same manner to make any necessary correction.

~~1 ml of 0.005 mol/L sodium thiosulfate = 0.1773 mg Cl~~

Scope of Hypochlorous Acid Water whose use is intended to be newly permitted (Shaded parts)

