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Japan

Food and Agricultural Import Regulations and Standards

Designation of Monoammonium L-Glutamate as Food Additive

2008

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Report Highlights:
On May 15, 2008, the Japanese Government announced the planned approval of new food additive, Monoammonium L-Glutamate. The comment period will close on May 29, 2008.

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

Summary
The Japanese Ministry of Health Labour and Welfare (MHLW) announced the planned approval of new food additive, Monoammonium L-Glutamate. The period for sending comments on these changes ends May 29. If you have comments it is best to send directly to MHLW as soon as possible, however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

The comments can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

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Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
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Designation of Monoammonium L-Glutamate as Food Additive

Outline

The Ministry of Health, Labour and Welfare is going to newly designate Monoammonium L-Glutamate as an authorized food additive.

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 prohibited to be marketed unless they meet these standards or specifications.

In the 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 Monoammonium L-Glutamate. The subcommittee has concluded as follows.

Conclusion from the subcommittee

The Minister should designate Monoammonium L-Glutamate, 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).

Additional Information

A list showing 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 2-2)

Attachment 2-1

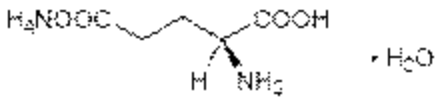
1. Standards for use

Not established.

2. Compositional specifications

Substance name Monoammonium L-Glutamate

Structural formula



Molecular formula $C_5H_{12}N_2O_5 \cdot H_2O$

Mol. Weight 182.18

Chemical name and CAS number
Monoammonium monohydrogen (2*S*)-2-aminopentanedioate monohydrate
[139888-82-2]

Content Contains not less than 99.0% of monoammonium L-glutamate ($C_5H_{12}N_2O_4 \cdot H_2O$), when calculated on the dried basis.

Description Colorless to white crystals or white crystalline powder.

Identification (1) Use a solution of Monoammonium L-Glutamate (1 in 200) as the test solution. Use a solution of 0.5 g of monosodium L-glutamate in 100 ml of water as the control solution. Analyze 1ml each of the test solution and the control solution by Thin-layer Chromatography using a 2:1:1 mixture of 1-butanol/water/acetic acid as the developing solution. Use a thin-layer plate coated with silica gel for thin-layer chromatography as the solid support and dried at 110°C for 1 hour. Stop the development when the solvent front ascends to a point about 10 cm above the original line, air-dry the plate, and then dry again for an additional 30 minutes at 80°C. Spray evenly with ninhydrin solution (1 in 500), and dry at 80°C for 10 minutes to develop color. Examine in daylight. The spot from the test solution is the same as the red-purple spot from the control solution in tone of color and Rf value.

(2) Monoammonium L-Glutamate responds to the test for Ammonium Salt in the Qualitative Tests.

Purity (1) Specific Rotation $[\alpha]_D^{20}$: +25.4 to +26.4° (10 g, hydrochloric acid (1 in 6), 100 ml, on the dried basis).

(2) pH 6.0–7.0 (1.0 g, water 20 ml).

(3) Lead Not more than 2.0 μg/g as Pb (5.0 g, Method 1).

(4) Arsenic Not more than 2.5 μg/g as As_2O_3 (0.80 g, Method 1, Apparatus B).

(5) Pyrrolidone carboxylic acid

Test Solution Dissolve 0.50 g of Monoammonium L-Glutamate, weighed exactly, in 100 ml of water.

Control Solution Dissolve 0.50 g of monosodium L-glutamate and 2.5 mg of pyrrolidone carboxylic acid in water to make exactly 100 ml.

Procedure Analyze 2 μl each of the test solution and the control solution by Thin-layer Chromatography using a 2:1:1 mixture of 1-butanol/water/acetic acid as the developing solution. Use a thin-layer plate coated with silica gel for thin-layer chromatography as the solid support and dried at 110°C for 1 hour. Stop the development when the solvent front ascends to a point about 10 cm above the original line, air-dry the plate, and then dry again for an additional 30 minutes at 120°C to remove the solvent.

Place the plate and a 50-ml beaker containing 5 ml of sodium hypochlorite into another developing chamber with the glass surface of the plate toward the beaker. Add gently about 2 ml of hydrochloric acid to the beaker to generate chlorine gas. Place a lid on the chamber, and allow to stand for 20 minutes. Put the plate out of the chamber, and allow to stand for another 10 minutes. Spray evenly with ethanol, and air-dry. Then spray with potassium iodide–starch TS, and examine in daylight. A spot from the control solution corresponds to pyrrolidone carboxylic acid. No spot corresponding to pyrrolidone carboxylic acid is observed for the test solution.

Loss on Drying Not more than 0.5% (50°C, 4 hours).

Residue on Ignition Not more than 0.1% (800°C, 15 minutes).

Assay Weigh accurately about 0.15 g of Monoammonium L-Glutamate, and proceed as directed in the Assay for L-Asparagine in the Monographs.

1 ml of 0.1 mol/L perchloric acid = 9.109 mg of $C_5H_{12}N_2O_4 \cdot H_2O$

<Reagents and Test Solutions>

Pyrrolidone Carboxylic Acid $C_5H_7NO_3$ White crystals or crystalline powder, and odorless.

Content Contains not less than 97.0% of 2-pyrrolidone 5-carboxylic acid ($C_5H_7NO_3$), when dried.

Identification Determine the absorption spectrum of Pyrrolidone Carboxylic Acid as directed in the Potassium Bromide Disk Method under Infrared Spectrophotometry. It exhibits absorption bands at wavenumbers of about 3400 cm^{-}, 1720 cm^{-}, 1655 cm^{-}, 1420 cm^{-}, and 1230 cm^{-}.

Loss on Drying Not more than 1.5% (105°C, 3 hours).

Assay Weigh accurately about 0.2 g of Pyrrolidone Carboxylic Acid, previously dried, and perform the assay by the Kjeldahl Method under Nitrogen Determination.

1 ml of 0.05 mol/L sulfuric acid = 12.91 mg of $C_5H_7NO_3$