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Japan

Food and Agricultural Import Regulations and Standards

Public Comment Period for New Food Additives- Ammonium alginate, Potassium alginate, and Calcium alginate

2006

Approved by:

Rachel Nelson
U.S. Embassy

Prepared by:

Rachel Nelson

Report Highlights:

On April 14th, 2006 the Japanese Ministry of Health, Labor and Welfare announced the intent to designate three new substances as approved food additives. Comments are being accepted until April 28th.

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

On April 14th, 2006 the Japanese Ministry of Health, Labor and Welfare announced the intent to designate three new substances as approved food additives. Comments are being accepted until April 28th. If you have comments please send them directly to the following address:

Standards and Evaluation Division, Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
Tel: 03-5253-1111
Fax: 03-3501-4868

Please also consider sending your comments, as early as possible, to the USDA Foreign agricultural Service (FSTSD@fas.usda.gov) for them to be considered for incorporation into official U.S. Government comments as well.

These three additives are part of the 46 substances that are generally considered safe around the world and are being reviewed systematically by MHLW and the FSC.

The text of the announcement follows:

Designation of Food Additives (Ammonium Alginate, Potassium Alginate and Calcium Alginate)

Purpose

This activity is to newly designate three substances (Ammonium Alginate, Potassium Alginate, and Calcium Alginate) as authorized food additives. Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. Where use standards or specifications are established for additives under Article 11 of the law, those additives may be marketed only when they meet the established standards or specifications.

In response to consultation by 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 these substances as food additive. The report from the subcommittee is outlined as below.

Outline

The Minister should designate Ammonium Alginate, Potassium Alginate, and Calcium Alginate based on Article 10 of the Food Sanitation Law as food additives not injurious to human health. Under Article 11 of the law, compositional specifications for these substances should be established. However, it is not necessary to establish use standards. The draft specifications are given in the attachment 1, 2 and 3.

Attachment 1

Ammonium Alginate

Standard for use: Will not be established.

Compositional specifications:

Substance name Ammonium Alginate

Chemical name, CAS number Ammonium Alginate [9005-34-9]

Content: It contains not less than 88.7–103.6% of ammonium alginate when calculated on the dried basis.

Description: It occurs as white to light yellowish brown filamentous, granular, or powdered forms.

Identification: (1) Prepare the test solution as follows. To 0.5 g of Ammonium Alginate, add 50 ml of water while stirring. Warm at 60–70°C for 20 minutes while stirring occasionally to make it uniformly, and cool.

(i) To 5 ml of the test solution, add 1 ml of calcium chloride solution (3? 40). A gelatinous precipitate is formed immediately.

(ii) To 1 ml of the test solution, add 1 ml of a saturated solution of ammonium sulfate. No precipitate is formed.

(2) Ammonium Alginate responds to the test for Ammonium Salt described in the Qualitative Tests.

Purity: (1) Water-insoluble matter Not more than 2.0% (on the dried basis).

Weigh accurately about 2 g of Ammonium Alginate in a 2,000-ml Erlenmeyer flask, add 800 ml of water, neutralize with sodium hydroxide TS, and then add additional 3 ml sodium hydroxide TS. Add 40 ml of hydrogen peroxide, cover the flask, and boil for 1 hour with frequent stirring. Filter while hot through a glass filter with a glass fiber filter paper by suction. The filter and filter paper should be previously dried at 105°C for about 1 hour, cooled in a desiccator, and accurately weighed. If slow filtration is caused by high viscosity of the sample solution, boil until the viscosity is reduced enough to permit filtration. Wash the filter with the filter paper thoroughly with hot water, dry them at 105°C for 1 hour, cool, and weigh accurately. Calculate as percentage of the dry weight.

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

(3) Arsenic Not more than 4.0 µg/g as As₂O₃ (0.50 g, Method 3, Apparatus B).

Loss on Drying: Not more than 15.0% (105°C for 4 hour).

Residue on Ignition: Not more than 7.0% (3 g, 800°C, 15 minutes, dried basis).

Microbial Limit: When the tests are conducted as directed under the Microbial Limit

Tests in the General Tests, the total plate count is not more than 5,000/g, and fungi (yeasts and moulds) count is not more than 500/g. Coliforms are negative.

Coliforms test: To 1 g of Ammonium Alginate, add fluid lactose broth medium or BGLB medium to make 100 ml. Depending on sample characteristics, the sample may be dispersed in more than the specified volume of liquid medium. If necessary, adjust its pH to 6–8, and incubate at 30–35°C for 24–72 hours. Examine the medium for growth, and if growth is present, and gently shake. Take a portion with a platinum loop, and streak it on the surface of MacConkey agar medium. Incubate at 30–35°C for 18–24 hours. If colonies of pink to red Gram-negative rod-shaped bacteria with a reddish surrounding precipitation zone are not found, the sample is determined to be negative for coliforms.

If colonies matching the above description are found, then transfer the suspect colonies individually on the surface of EMB agar medium, and incubate at 30–35°C for 18–24 hours. If typical colonies with a metallic sheen or dark purple-red color are not found, the sample is determined to be negative for coliforms. Confirm suspect coliforms on the plates as follows. Transfer them to fermentation vials of lactose broth medium, and incubate at 30–35°C for 18–48 hours. Gas forming, Gram-negative, non-spore-forming, rod-shaped bacteria in the vial are judged as coliforms. Rapid detection kits for coliforms may be used.

Effectiveness of culture media and confirmation of anti-microbial substances:
Use an appropriate one out of Escherichia coli strains (NBRC 3972, ATCC 8739, NCIMB 8545) and their equivalents. Incubate it in lactose broth medium, fluid soybean-casein digest medium, or soybean-casein digest agar medium at 30–35°C for 18–24 hours. Prepare a suspension containing about 1,000 viable bacteria per ml by diluting the incubated culture with sodium chloride-peptone buffer solution, phosphate buffer, or lactose broth agar medium. Mix 0.1 ml of this suspension with the medium to be used for the test, and examine the effectiveness of medium and the presence of anti-microbial substances both in presence and absence of the sample.

Assay

Proceed as directed under Assay for Alginic Acid in Monographs.
1 ml of 0.25 mol/L sodium hydroxide = 27.12 mg of ammonium alginate

Attachment 2

Potassium Alginate

Standard for use: Will not be established.

Compositional specifications

Substance name: Potassium Alginate
Chemical name, CAS number Potassium Alginate [9005-36-1]

Content: It contains not less than 89.2–105.5% of ammonium alginate when calculated on the dried basis.

Description: It occurs as white to light yellowish white filamentous, granular, or powdered forms.

Identification: (1) Prepare the test solution as follows. To 0.5 g of Ammonium Alginate, add 50 ml of water while stirring. Warm at 60–70°C for 20 minutes while stirring occasionally to make it uniformly, and cool.

(i) To 5 ml of the test solution, add 1 ml of calcium chloride solution (3? 40). A gelatinous precipitate is formed immediately.

(ii) To 1 ml of the test solution, add 1 ml of a saturated solution of ammonium sulfate. No precipitate is formed. (2) Ignite 1 g of Potassium Alginate at 550–600°C for 3 hours, and to the residue, add 10 ml of water. The obtained solution responds to all the tests for Potassium Salt described in the Qualitative Tests.

Purity: (1) Water-insoluble matter Not more than 2.0% (on the dried basis).

Weigh accurately about 2 g of Ammonium Alginate in a 2,000-ml Erlenmeyer flask, add 800 ml of water, neutralize with sodium hydroxide TS, and then add additional 3 ml sodium hydroxide TS. Add 40 ml of hydrogen peroxide, cover the flask, and boil for 1 hour with frequent stirring. Filter while hot through a glass filter with a glass fiber filter paper by suction. The filter and filter paper should be previously dried at 105°C for about 1 hour, cooled in a desiccator, and accurately weighed. If slow filtration is caused by high viscosity of the sample solution, boil until the viscosity is reduced enough to permit filtration. Wash the filter with the filter paper thoroughly with hot water, dry them at 105°C for 1 hour, cool, and weigh accurately. Calculate as percentage of the dry weight.

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

(3) Arsenic Not more than 4.0 µg/g as As₂O₃ (0.50 g, Method 3, Apparatus B).

Loss on Drying Not more than 15.0% (105°C for 4 hour).

Microbial Limit: When the tests are conducted as directed under the Microbial Limit Tests in the General Tests, the total plate count is not more than 5,000/g, and fungi (yeasts and moulds) count is not more than 500/g. Coliforms are negative.

Coliforms test To 1 g of Potassium Alginate, add fluid lactose broth medium or BGLB medium to make 100 ml. Depending on sample characteristics, the sample may be dispersed in more than the specified volume of liquid medium. If necessary, adjust its pH to 6–8, and incubate at 30–35°C for 24–72 hours. Examine the medium for growth, and if growth is present, and gently shake. Take a portion with a platinum loop, and streak it on the surface of MacConkey agar medium. Incubate at 30–35°C for 18–24 hours. If colonies of pink to red Gram-negative rod-shaped bacteria with a reddish surrounding precipitation zone are not found, the sample is determined to be negative for coliforms.

If colonies matching the above description are found, then transfer the suspect colonies individually on the surface of EMB agar medium, and incubate at 30–35°C for 18–24 hours. If typical colonies with a metallic sheen or dark purple-red color are

not found, the sample is determined to be negative for coliforms.

Confirm suspect coliforms on the plates as follows. Transfer them fermentation vials of lactose broth medium, and incubate at 30–35°C for 18–48 hours. Gas forming, Gram-negative, non-spore-forming, rod-shaped bacteria in the vial are judged as coliforms. Rapid detection kits for coliforms may be used.

Effectiveness of culture media and confirmation of anti-microbial substances:

Use an appropriate one out of Escherichia coli strains (NBRC 3972, ATCC 8739, NCIMB 8545) and their equivalents. Incubate it in lactose broth medium, fluid soybean-casein digest medium, or soybean-casein digest agar medium at 30–35°C for 18–24 hours. Prepare a suspension containing about 1,000 viable bacteria per ml by diluting the incubated culture with sodium chloride-peptone buffer solution, phosphate buffer, or lactose broth agar medium. Mix 0.1 ml of this suspension with the medium to be used for the test, and examine the effectiveness of medium and the presence of anti-microbial substances both in presence and absence of the sample.

Assay:

Proceed as directed under Assay for Alginic Acid in Monographs.

1 ml of 0.25 mol/L sodium hydroxide = 29.75 mg of potassium alginate

Attachment 3

Calcium Alginate

Standard for use: Not established.

Compositional specifications

Substance name: Calcium Alginate

Chemical name, CAS number Calcium Alginate [9005-35-0]

Content: It contains not less than 89.6–104.5% of calcium alginate when calculated on the dried basis.

Description: It occurs as white to light yellowish white filamentous, granular, or powdered forms.

Identification: (1) Prepare the test solution as follows. To 0.25 g of Calcium Alginate, add 50 ml of sodium carbonate solution (1? 400) while stirring. Warm at 60–70°C for 20 minutes while stirring occasionally to make it uniformly, and cool.

(i) To 5 ml of the test solution, add 1 ml of calcium chloride solution (3? 40). A gelatinous precipitate is formed immediately.

(ii) To 1 ml of the test solution, add 1 ml of a saturated solution of ammonium sulfate. No precipitate is formed.

(2) Ignite 1 g of Calcium Alginate at 550–600°C for 3 hours, to the residue add 10

ml of water and 5 ml of acetic acid (1? 3) to dissolve, and filter if necessary. Boil it, cool, and neutralize with ammonia TS. The obtained solution responds to all the tests for Calcium Salt described in the Qualitative Tests.

Purity: (1) Lead Not more than 5.0 µg/g as Pb (2.0 g, Method 1).
(2) Arsenic Not more than 4.0 µg/g as As₂O₃ (0.50 g, Method 3, Apparatus B).

Loss on Drying: Not more than 15.0% (105°C for 4 hour).

Microbial Limit: When the tests are conducted as directed under the Microbial Limit Tests in the General Tests, the total plate count is not more than 5,000/g, and fungi (yeasts and moulds) count is not more than 500/g. Coliforms are negative.

Coliforms test To 1 g of Calcium Alginate, add fluid lactose broth medium or BGLB medium to make 100 ml. Depending on sample characteristics, the sample may be dispersed in more than the specified volume of liquid medium. If necessary, adjust its pH to 6–8, and incubate at 30–35°C for 24–72 hours. Examine the medium for growth, and if growth is present, gently shake. Take a portion with a platinum loop, and streak it on the surface of MacConkey agar medium. Incubate at 30–35°C for 18–24 hours. If colonies of pink to red Gram-negative rod-shaped bacteria with a reddish surrounding precipitation zone are not found, coliforms are negative.

If colonies matching the above description are found, then transfer the suspect colonies individually on the surface of EMB agar medium, and incubate at 30–35°C for 18–24 hours. If typical colonies with a metallic sheen or dark purple-red color are not found, the sample is determined to be negative.

Confirm suspect coliforms on the plates as follows. Transfer them fermentation vials of lactose broth medium, and incubate at 30–35°C for 18–48 hours. Gas forming, Gram-negative, non-spore-forming, rod-shaped bacteria in the vial are judged as coliforms. Rapid detection kits for coliforms may be used.

Effectiveness of culture media and confirmation of anti-microbial substances:

Use an appropriate one out of Escherichia coli strains (NBRC 3972, ATCC 8739, NCIMB 8545) and their equivalents. Incubate it in lactose broth medium, fluid soybean-casein digest medium, or soybean-casein digest agar medium at 30–35°C for 18–24 hours. Prepare a suspension containing about 1,000 viable bacteria per ml by diluting the incubated culture with sodium chloride-peptone buffer solution, phosphate buffer, or lactose broth agar medium. Mix 0.1 ml of this suspension with the medium to be used for the test, and examine the effectiveness of medium and the presence of anti-microbial substances both in presence and absence of the sample.

Assay:

Proceed as directed under Assay for Alginic Acid in Monographs.

1 ml of 0.25 mol/L sodium hydroxide = 27.38 mg of calcium alginate