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Japan Announces Approval of Two New Food Additives (Calcium Acetate and Calcium Oxide)

Report Categories:
Sanitary/Phytosanitary/Food Safety
Approved By:
Jennifer Clever
Prepared By:
Suguru Sato

Report Highlights:
On March 25, 2013, the Government of Japan (GOJ) proposed the approval of two new food additives, calcium acetate and calcium oxide. The Embassy comment period on this proposal will close on April 8, 2013. After that, there will be a domestic public comment period and a WTO notification by MHLW. These will be other opportunities for interested parties to comment on this subject.

General Information:

On March 25, 2013, the Government of Japan (GOJ) announced the approval of two new food additive, calcium acetate and calcium oxide. The Embassy comment period for these changes will close on April 8, 2013. After that, there will be a domestic public comment period and a WTO notification by MHLW. These will be other opportunities for interested parties to comment on this subject.

Any parties interested in submitting comments to MHLW should do so as soon as possible.

MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide an additional chance for interested parties to submit comments on this subject. The actual WTO/SPS notifications can be found at the site below.

http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm

After the WTO comment period closes, a final report will be released based on the conclusions reached by a session of the Pharmaceutical Affairs and Food Sanitation Council scheduled to be held at a later date. The Council's report will constitute the final decision.

Comments to the GOJ can be made either in Japanese or English and can be sent to the below points of contact:

Hiromi MATSUDA, Ms.
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, ext. 2459
Fax: 03-3501-4868
matsuda-hiromi@mhlw.go.jp

Post requests that the U.S. Embassy - Tokyo also be copied on any comments at agtokyo@usda.gov to allow them to be considered as part of the official U.S. Government comments to the WTO.

Designation of Food Additives

Japan is going to designate Calcium Acetate and Calcium Oxide as authorized additives.

Under Article 10 of the Food Sanitation Act, food additives shall not be used or marketed without authorization by the Minister of Health, Labour and Welfare. When compositional specifications or standards for use or manufacturing are established for food additives based on Article 11 of the act, those additives shall not be used or marketed unless they meet the standards or specifications.

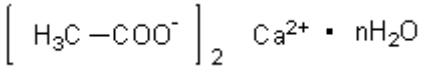
In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of Calcium Acetate [CAS No. 5743-26-0 (monohydrate) and CAS No. 62-54-4 (anhydrous)] and Calcium Oxide [CAS No. 1305-78-8]. The committee concluded as follows:

The Minister should designate Calcium Acetate and Calcium Oxide based on Article 10 of Food Sanitation Act as food additives unlikely to harm human health, and establish compositional specifications for them based on Article 11 of the act. See Attachments 1 and 2.

Calcium Acetate is used abroad mainly as a preservative, pH regulator, or nutritional enhancer. Calcium Oxide is used abroad mainly as bread dough regulator, yeast food, or nutritional enhancer.

Attachment 1

Calcium Acetate
酢酸カルシウム



n = 1 or 0

Standard for use
Not established.

Compositional specifications
Substance name Calcium Acetate
Molecular formula $C_4H_6CaO_4 \cdot nH_2O$ (n＝1 or 0)
Mol. Weight 176.18 (monohydrate), 158.17 (anhydrous)
hemical name [CAS number]
Calcium acetate monohydrate [5743-26-0]
Calcium acetate [62-54-4]
Content Calcium Acetate, when dried, contains not less than 98.0% of calcium acetate ($C_4H_6CaO_4$).
Description Calcium Acetate occurs as white, hygroscopic crystals or white powder or granules. It has a slight odor of acetic acid.
Identification
Calcium Acetate responds to all tests for Calcium Salt and Acetate in the Qualitative Tests.
Purity
(1) pH 6.0−9.0 (2.0 g, water 20 ml).
(2) Water-insoluble substances: Not more than 0.3 %.
Weigh accurately a crucible-type glass filter (1G4), previously dried at 105ºC for 30 minutes and cooled in a desiccators. Weigh accurately about 10 g of Calcium Acetate, add 10 ml of warm water, and agitate. Filter it through the glass filter, and wash the residue on the filter with 30 ml of water. Dry the filter containing the residue at 105 ºC for 2 hours, cool in desiccators, and weigh the filter accurately.

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

Test Solution Weigh exactly 2.0 g of Calcium Acetate into a 100-ml beaker, add 20 ml of diluted hydrochloric acid (1 in 4), and dissolve it by ultrasonic agitation. Evaporate to dryness, and dissolve the residue in 20 ml of water. Use the resulting solution as the sample solution. To the sample solution, add 50 ml of a solution of diammonium hydrogen citrate (1 in 2), then add ammonia solution until the color of the solution changes to yellow-green using 1 ml of thymol blue as the indicator. Transfer the resulting solution into a 200-ml separating funnel, wash the beaker with water, add the washings to the funnel, and make about 100 ml. To this solution, add 5 ml of ammonium pyrrolidine dithiocarbamate (3 in 100), and allow to stand for 5 minutes. Add exactly 10 ml of butyl acetate, agitate for 5 minutes, and allow to stand. Use the butyl acetate layer as the test solution.

Control Solution Measure exactly 1 ml of Lead Standard Solution, and add water to make exactly 100 ml. Measure exactly 4 ml of this solution, and proceed in the same manner as for the sample solution.

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

(4) Arsenic : Not more than 4.0 μg/g as As_2O_3 (0.50 g, Method 1, Apparatus B).

(5) Readily oxidizable substances : Not more than 1000 μg/g as HCOOH.

Weigh accurately about 5 g of Calcium Acetate, add 100 ml of water to dissolve, then add 0.5 g of anhydrous sodium carbonate, and shake. Add exactly 10 ml of 0.02 mol/L potassium permanganate, shake, and heat on a water bath for 15 minutes. After cooling, add 25 ml of diluted sulfuric acid (9 in 100) and 0.3 g of potassium iodide, shake well, and titrate with 0.1 mol/L sodium thiosulfate (indicator: starch TS). When the color of the solution becomes yellowish white near the endpoint, add 3 ml of starch TS. The end point is when the solution is decolored. Separately, perform a blank test. Calculate the content of readily oxidizable substances (HCOOH) by the formula:

$$\text{Content (μg/g) of readily oxidizable substances} = \frac{(a-b)\times 2301}{\text{Weight of the sample}}$$

Loss on Drying Not more than 11.0% (155ºC, Constant weight)

Assay

Test Solution and Procedure Weigh accurately about 4 g of Calcium Acetate, previously dried, add 30 ml of diluted hydrochloric acid (1 in 4) to dissolve, then add water to make exactly 250 ml. Use this solution as the test solution. Proceed as directed in Method 1 under Calcium Salt Determination.

Each ml of 0.05mol/L EDTA = 7.908 mg of $C_4H_6CaO_4$

Attachment 2

Calcium Oxide
酸化カルシウム

Standard for use

Not established.

Compositional specifications

Substance name Calcium Oxide

Molecular formula CaO

Mol. Weight 56.08

hemical name [CAS number]

Calcium oxide [1305-78-8]

Content Calcium Oxide, when ignited, contains not less than 95.0% of calcium oxide (CaO).

Description Calcium Oxide occurs as white to light gray powder, granules, or lumps.

Identification

1. When moistened with water, 1 g of Calcium Oxide generates heat. To this, add 5 ml of water. The resulting suspension is alkaline.
2. To 1 g of Calcium Oxide, add 20 ml of water, and add acetic acid dropwise until the precipitate dissolves. The resulting solution responds to all tests for Calcium salts in the Qualitative Tests.

Purity

(1) Hydrochloric acid insoluble substances : Not more than 1.0%

Weigh accurately a crucible-type glass filter (1G4), previously dried at 105ºC for 30 minutes and cooled in a desiccators. Weigh exactly 5.0 g of Calcium Oxide, moisten with water, and add 100 ml of water. Add hydrochloric acid dropwise while shaking until the sample no longer dissolves, and boil. After cooling, add hydrochloric acid if necessary to make it acidic. Filter it through the glass filter, wash the residue on the filter with water until the washings are free of chlorides. Dry the filter containing the residue at 105 ºC for 1 hour, cool in desiccators, and weigh the filter accurately.

(2) Fluoride: Not more than 150 μg/g as F.

Test Solution Weigh exactly 0.10 g of Calcium Oxide into a beaker, and add 10 ml of diluted hydrochloric acid (1 in 10) to dissolve. Heat it, boil for 1 minute, transfer into a polyethylene beaker, and immediately cool in ice. Add 15 ml of sodium citrate solution (1 in 4) and 10 ml of disodium ethylenediaminetetraacetate, and mix it. Then, adjust the pH to 5.4–5.6 with diluted hydrochloric acid (1 in 10) or sodium hydroxide solution (2 in 5). Transfer the resulting solution into a 100-ml measuring flask, and dilute with water to volume. Transfer 50 ml of this solution into a polyethylene beaker.

Control Solution Measure exactly 5 ml of Fluoride Ion Standard Stock Solution into a 1000-ml measuring flask, and dilute with water to volume. Transfer exactly 3 ml of this solution into a polyethylene beaker, add 15 ml of sodium citrate solution (1 in 4) and 10 ml of disodium ethylenediaminetetraacetate, and mix it. Then, adjust the pH to 5.4–5.6 with diluted hydrochloric acid (1 in 4) or sodium hydroxide solution (2 in 5). Transfer the resulting solution into a 100-ml measuring flask, and dilute with water to volume. Transfer 50 ml of this solution into a polyethylene beaker.

Procedure Measure the potential of the test solution and the control solution using a potentiometer connected to a reference electrode and a fluoride ion electrode. The potential of the test solution is not less than that of the control solution.

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

Test Solution Weigh exactly 2.0 g of Calcium Acetate into a 100-ml beaker, add 20 ml of diluted hydrochloric acid (1 in 4) little by little, and dissolve by ultrasonic agitation. Evaporate to dryness, and dissolve the residue in 20 ml of water. Use the resulting solution as the sample solution. To the sample solution, add 50 ml of a solution of diammonium hydrogen citrate (1 in 2), then add ammonia solution until the color of the solution changes to yellow-green using 1 ml of thymol blue as the indicator. Transfer the resulting solution into a 200-ml separating funnel, wash the beaker with water, add the washings to the separating funnel, and make about 100 ml. To this solution, add 5 ml of ammonium pyrrolidine dithiocarbamate (3 in 100), and allow to stand for 5 minutes. Add exactly 10 ml of butyl acetate, agitate for 5 minutes, and allow to stand. Use the butyl acetate layer as the test solution.

Control Solution Measure exactly 1 ml of Lead Standard Solution, and add water to make exactly 100 ml. Measure exactly 4 ml of this solution, and proceed in the same manner as for the sample

solution.

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

(4) Alkali metals and magnesium : Not more than 3.6%.

Weigh about 0.5 g of Calcium Oxide, dissolve by adding 30 ml of water and 15 ml of diluted hydrochloric acid (1 in 4), and boil for 1 minute. Immediately add 40 ml of tartalic acid solution (3 in 50), agitate, and neutralize with ammonia solution. Heat this solution on a water bath for 1 hour, cool, and add water to make 100 ml. Mix well, and filter. Transfer 50 ml of the filtrate into a platinum crucible, previously ignited at 800°C for 30 minutes, cooled in a desiccator, and weighed accurately. Evaporate with 0.5 ml of sulfuric acid, ignite at 800°C to constant weight, and weigh the crucible to determine the weight of the residue.

(5) Barium : Not more than 300 μg /g as Ba.

Test Solution Weigh accurately about 1.0 g of Calcium Oxide, add diluted hydrochloric acid (1 in 10) to dissolve, and make exactly 50 ml. Measure 5 ml of this solution, and add diluted nitric acid (1 in 150) to make exactly 100 ml.

Control Solution Measure exactly 1 ml of Barium Standard Solution, and add diluted nitric acid (1 in 150) to make exactly 1000 ml. Measure exactly 30 ml of this solution, and add diluted nitric acid (1 in 150) to make exactly 100 ml.

Procedure Proceed as directed under Inductively Coupled Plasma-Atomic Emission Spectrometry. The emission intensity of the test solution is not more than that of the control solution.

(6) Arsenic: Not more than 4.0 μg/g as As_2O.

Test Solution Weigh 0.50 g of Calcium Oxide, and add 8 ml of diluted hydrochloric acid (1 in 4) to dissolve.

Apparatus Use Apparatus B.

Loss on Ignition Not more than 10.0 % (800°C, constant weight).

Assay

Test solution and Procedure

Weigh accurately about 1.5 g of Calcium Oxide, previously ignited, add 30 ml of diluted hydrochloric acid (1 in 4) to dissolve, and add water to make exactly 250 ml. Use the resulting solution as the test solution. Proceed as directed under Method 1 in Calcium Determination.

Each ml of 0.05 mol/L EDTA = 2.804 mg of CaO

Regents and Solutions

Fluoride Ion Standard Stock Solution Weigh 2.210 g of sodium fluoride, previously dried at 110°C for 2 hours, into a polyethylene beaker, add water 200 ml, and dissolve while stirring. Transfer this solution into a 1000 ml of measuring flask, and dilute with water to volume. Each ml of this solution contains 1 mg of fluorine (F). Store in a polyethylene container.