Voluntary _ Public

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Designation of Four Substances as Food Additives

Report Categories:
Sanitary/Phytosanitary/Food Safety

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Report Highlights:
On December 12, 2011, the Japanese Government announced it would designate four new food additives (3-Amino-3-carboxypropyl) dimethylsulfonium chloride, 2-Ethyl-6-methylpyrazine, Trimethylamine and trans-2-Methyl-2-butenal. The domestic comment period will closed on December 26, 2011, however MHLW will also notify these proposed changes to the WTO/SPS committee.

General Information:
On December 12, 2011, the Japanese Government announced plans to designate four new food additives, (3-Amino-3-carboxypropyl) dimethylsulfonium chloride, 2-Ethyl-6-methylpyrazine, Trimethylamine and trans-2-Methyl-2-butenal. The domestic comment period will close on December 26, 2011, 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.

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 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; this will constitute the final decision.

The comments to GOJ can be either Japanese or English. GOJ point of contact for the comment is indicated below.
If you have comments, please send them directly to the Japanese Government at:

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Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Designation of Food Additives and Revision of Use Standards

Summary
The Ministry of Health, Labour and Welfare is going to newly designate five substances as authorized food additives. They are four flavoring agents ((3-Amino-3-carboxypropyl)dimethylsulfonuim Chloride, 2-Ethyl-6-methylpyrazine, Trimethylamine, trans-2-Methyl-2-butenal).

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. 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 used or marketed unless they meet these 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 designation of these substances as food additives. The conclusion of the committee is outlined below.

Outline of conclusion

The Minister may designate (3-Amino-3-carboxypropyl) dimethylsulfonuim Chloride, 2-Ethyl-6-methylpyrazine, Trimethylamine, trans-2-Methyl-2-butenal based on Article 10 of the Food Sanitation Law, as food additives unlikely to harm human health and establish compositional specifications and use standards for these substances, based on Article 11 of the law (see Attachments 2-1 to 2-4).

(3-Amino-3-carboxypropyl)dimethylsulfonium Chloride

(3-アミノ-3-カルボキシプロピル)ジメチルスルホニウム塩化物

Standard for use

It shall not be used for purposes other than flavoring.

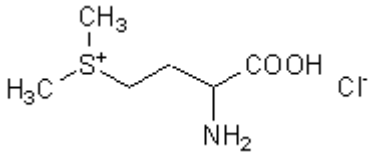
Compositional specifications

Substance name

(3-Amino-3-carboxypropyl)dimethylsulfonium Chloride

Synonym: Methylmethioninesulfonium Chloride

Structural formula



Molecular formula $C_6H_{14}ClNO_2S$

Mol. Weight 199.70

hemical name [CAS number]

(3-Amino-3-carboxypropyl)dimethylsulfonium Chloride [3493-12-7]

Content (3-Amino-3-carboxypropyl)dimethylsulfonium Chloride contains not less than 98.0% of (3-amino-3-carboxypropyl)dimethylsulfonium chloride ($C_6H_{14}ClNO_2S$).

Description (3-Amino-3-carboxypropyl)dimethylsulfonium Chloride occurs as white crystals or powder having a characteristic odor.

Identification Allow (3-Amino-3-carboxypropyl)dimethylsulfonium Chloride to stand in a desiccator for 3 hours, and determine the infrared absorption spectrum as directed in the Paste Method under Infrared Spectrophotometry. Use optical plates made from sodium chloride. Compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

Purity Melting point 138–143°C (decomposition).

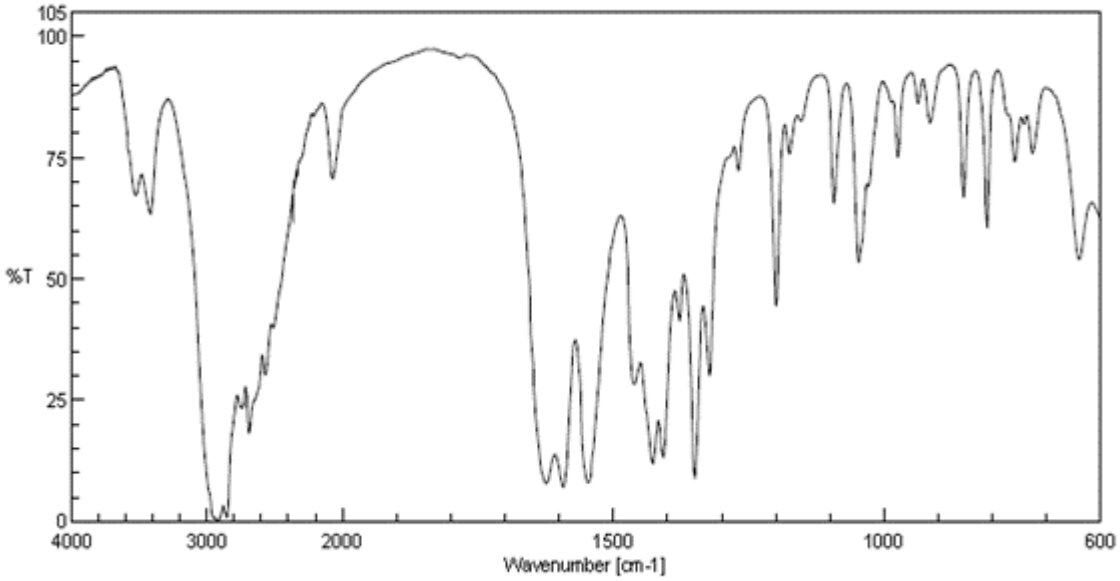
Assay Weigh accurately about 0.3 g of (3-Amino-3-carboxypropyl)dimethylsulfonium Chloride,

previously dried, dissolve by adding 70 ml of water and 1 ml of 0.1 mol/L hydrochloric acid, and titrate with 0.1 mol/L potassium hydroxide (potentiometric titration). Determine the content using the volume of 0.1 mol/L potassium hydroxide consumed between the first and second inflection points.

Each ml of 0.1 mol/L potassium hydroxide = 19.970 mg of $C_6H_{14}ClNO_2S$

IR Spectrum

3-Amino-3-carboxypropyl)dimethylsulfonium Chloride



2-Ethyl-6-methylpyrazine

2-エチル-6-メチルピラジン

Standard for use

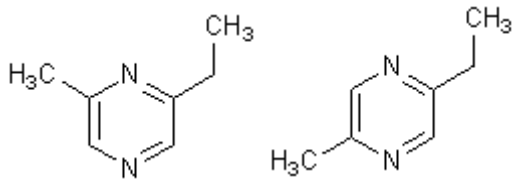
It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name

2-Ethyl-6-methylpyrazine

Structural formula



Molecular formula $C_7H_{10}N_2$
Mol. Weight 122.17
hemical name [CAS number]

Mixture of 2-ethyl-6-methylpyrazine and 2-ethyl-5-methylpyrazine [36731-41-6]

Definition 2-Ethyl-6-methylpyrazine occurs as the mixture of 2-ethyl-6-methylpyrazine and 2-ethyl-5-methylpyrazine.

Content 2-Ethyl-6-methylpyrazine contains not less than 95.0% of the sum of 2-ethyl-6-methylpyrazine and 2-ethyl-5-methylpyrazine ($C_7H_{10}N_2$).

Description 2-Ethyl-6-methylpyrazine occurs as a colorless to pale yellow, transparent liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2-Ethyl-6-methylpyrazine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

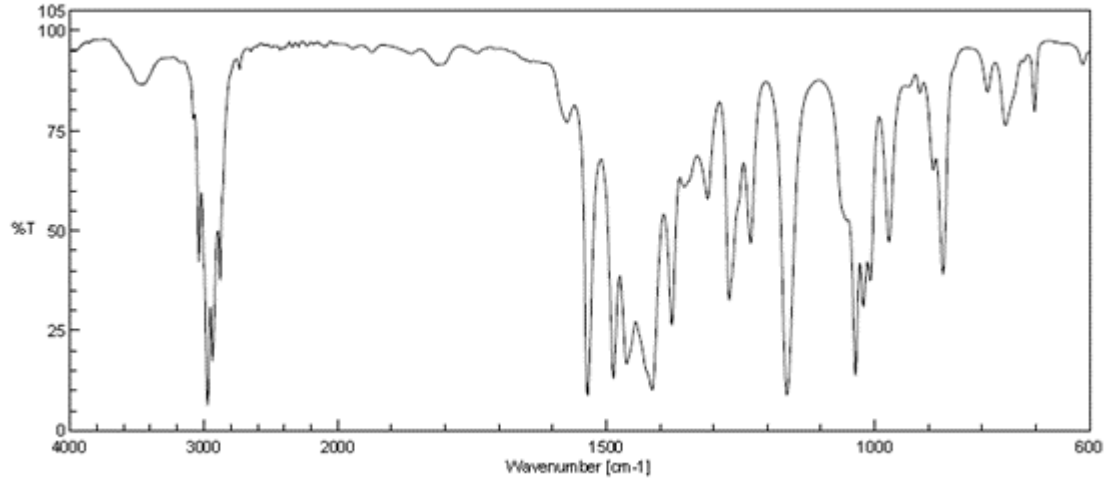
Purity (1) Refractive index n_D^{20} : 1.492–1.502.

(2) Specific gravity d_{25}^{25} : 0.960–0.973.

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1).

IR Spectrum

2-Ethyl-6-methylpyrazine



Trimethylamine

トリメチルアミン

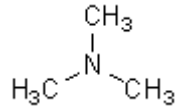
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name Trimethylamine

Structural formula



Molecular formula C_3H_9N

Mol. Weight 59.11

Chemical name [CAS number] Trimethylamine [75-50-3]

Content Trimethylamine contains not less than 98.0% of trimethylamine (C_3H_9N).

Description Trimethylamine occurs as a colorless gas having a characteristic odor.

Identification Carry out the test as directed in the Assay. The mass spectrum of the main peak include a molecular ion peak (m/z 59), a standard peak (m/z 58), and fragment peaks (m/z 15, m/z 30, m/z 42).

Assay To 1 ml of water cooled to 0–4°C, add 0.1 g of Trimethylamine, previously cooled to −20°C, and dissolve it. Analyze the resulting solution by gas chromatography using operating conditions given below. Determine the peak area percentage of the component to be determined by normalizing the sum of the areas of all peaks, excluding those from water, that appear within 40 minutes after injection as 100.

tector: Mass spectrometer (electron impact ionization method)

ass scanning range: m/z 10.00–300.00

lumn: Use a silicate-glass capillary tube (0.25–0.53 mm internal diameter and 50–60 m length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane or polyethylene glycol for gas chromatography.

lumn temperature: Maintain the temperature for 5 minutes at 50°C, and raise to 230°C at a rate of 5°C/minute.

et temperature: 125–175°C.

erface temperature: Highest column temperature (230°C)–highest applicable temperature.

ection: Sprit (30:1–250:1). Adjust so that any component does not exceed the acceptable level of the column used.

rrier gas: Helium.

Flow rate: Adjust so that the peak of the component to be determined appears between 3–20 minutes after injection.

trans-2-Methyl-2-butenal

(*E*)-2-Methyl-2-butenal

trans-2-メチル-2-ブテナール

Standard for use

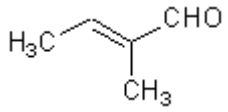
It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name *trans*-2-Methyl-2-butenal

Synonym: (*E*)-2-Methyl-2-butenal

Structural formula



Molecular formula C_5H_8O

Mol. Weight 84.12

hemical name [CAS number] (2*E*)-2-Methylbut-2-enal [497-03-0]

Content *trans*-2-Methyl-2-butenal contains not less than 97.0% of *trans*-2-methyl-2-butenal (C_5H_8O).

Description *trans*-2-Methyl-2-butenal occurs as a colorless, transparent liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of *trans*-2-Methyl-2-butenal as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

Purity (1) Refractive index n_D^{20}: 1.445–1.450.

(2) Specific gravity d_{20}^{20}: 0.866–0.873.

(3) Acid value Not more than 3.0 (Flavor Substance Tests).

Assay With a solution of *trans*-2-Methyl-2-butenal in acetone (1 in 10), proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2). Use the following operating conditions. Determine the peak area percentage of the component to be determined by normalizing the sum of the peak areas of all components that appear within 60 minutes after injection as 100.

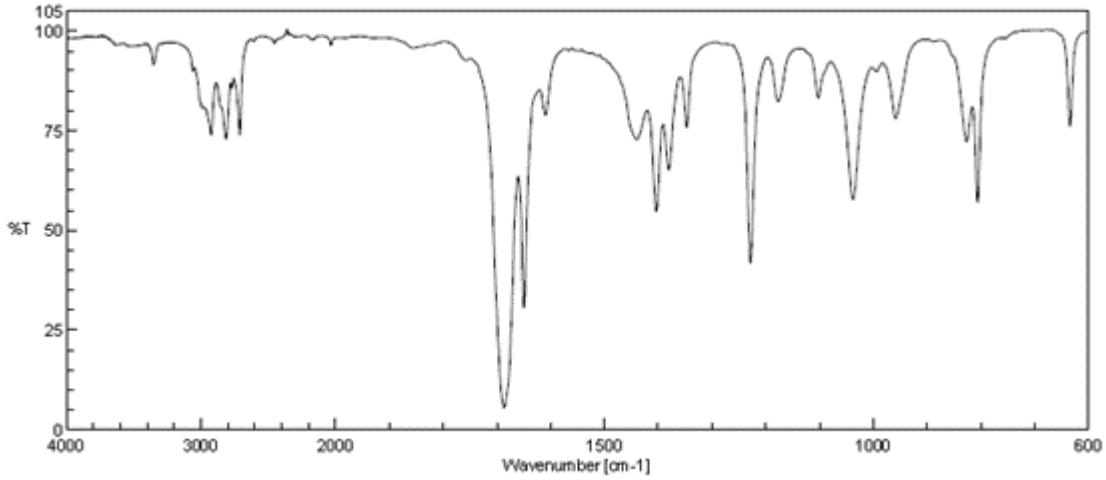
lumn: Use a silicate-glass capillary tube (0.25–0.53 mm in internal diameter and 50–60 m in length) coated with a 0.5–1 μm thick layer of polyethylene glycol for gas chromatography.

lumn temperature: Maintain the temperature for 15 minutes at 50°C, raise to 230°C at a rate of 10°C/minute, and maintain for 27 minutes.

ow rate: Adjust so that the peak of the component to be determined appears between 10–30 minutes after injection.

IR Spectrum

trans-2-Methyl-2-butenal


105
100
75
%T 50
25
0
4000
3000
2000
1500
1000
600
Wavenumber [cm-1]