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Japan Proposes New MRLs for Phenthoate and New Additives

Report Categories:
Sanitary/Phytosanitary/Food Safety

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Report Highlights:
On December 12, 2012, the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for phenthoate. The Ministry of Health, Labor and Welfare (MHLW) also proposed the approval of two new food additives, potassium lactate, and potassium sulfate, as well as a revision to the compositional specification in 5-methylquinoxaline. The Embassy comment period for these changes will close on Wednesday, December 26, 2012. 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 comments on this subject.

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Any parties interested in submitting comments to MHLW should do so as soon as possible. In the case of MRL changes, if you are requesting that Japan adopt the same limits as the U.S. maximum residue limits, the request should be accompanied by data supporting U.S. MRLs, such as risk assessment and residue data. The information MHLW requires would include toxicity data for target chemicals, residue trial data that support the MRLs, and target food commodities. Please be advised that Limit of Quantitation (LOQ) and Limit of Detection (LOD) data cannot be used as reference data to set up Japanese MRLs. For Japan's MRLs and the details of the information MHLW needs, please visit the following MRLs websites:

Pesticides; http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/01.pdf
Feed additives; http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/02.pdf
Veterinary drugs; http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/03.pdf

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 point of contacts:

Comments pertaining to changes in MRLs
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Comments pertaining to changes in food additives

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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.

Item 1. Setting of Maximum Residue Limits for Phenthoate in Food

The Ministry of Health, Labour and Welfare (MHLW) is going to develop compositional specifications for food.

Summary

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour and Welfare is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just "agricultural chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless it complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has comprehensively reviewed the current MRLs for Phenthoate. Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Phenthoate (insecticide): Permitted for use in Japan.

Currently, this compound is permitted for use only on *unshu* orange (pulp) for the citrus fruit category. The Ministry of Agriculture, Forestry and Fisheries (MAFF) has decided to allow its

application even to other citrus fruits. In response to the MAFF's action, the MHLW has established new MRLs for these citrus fruits.

In addition, the MHLW has reviewed the MRLs that had been provisionally established at the introduction of the positive list system.

Phenthoate

Commodity	MRL (draft) ppm	MRL (current) ppm
Rice (brown rice)	0.05	0.05
Wheat	0.5	0.4
Barley		0.4
Rye		0.4
Corn (maize, including pop corn and sweet corn)	0.02	0.4
Buckwheat		0.4
Other cereal grains		0.4
Soybeans, dry	0.05	0.05
Beans, dry (including butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans)	0.05	0.05
Peas	0.05	0.05
Broad beans	0.02	0.05
Peanuts, dry		0.05
Other legumes/pulses	0.05	0.05
Potato	0.02	0.05
Taro	0.02	0.05
Sweet potato	0.02	0.05
Yam		0.05
Konjac		0.05
Other potatoes		0.05
Japanese radish, roots (including radish)	0.02	0.1
Japanese radish, leaves (including radish)	0.02	0.1
Turnip, roots (including rutabaga)	0.02	0.1
Turnip, leaves (including rutabaga)	0.02	0.1
Horseradish		0.1
Watercress		0.1
Chinese cabbage	0.02	0.1
Cabbage	0.02	0.1
Brussels sprouts		0.1
Kale		0.1
Komatsuna(Japanese mustard spinach)		0.1
Kyona		0.1
Qing-geng-cai		0.1

Cauliflower	0.02	0.1
Broccoli	0.05	0.1
Other cruciferous vegetables		0.1
Burdock	0.02	0.1
Salsify		0.1
Artichoke		0.1
Chicory		0.1
Endive		0.1
Shungiku		0.1
Lettuce (including cos lettuce and leaf lettuce)	0.1	0.1
Other composite vegetables		0.1
Onion	0.02	0.1
Welsh (including leek)	0.05	0.1
Garlic		0.1
Nira		0.1
Asparagus	0.05	0.1
Multiplying onion (including shallot)	0.1	0.1
Other liliaceous vegetables	0.02	0.1
Carrot	0.1	0.1
Parsnip		0.1
Parsley		0.1
Celery		0.1
Mitsuba		0.1
Other umbelliferous vegetables		0.1
Tomato		0.1
Pimiento (sweet pepper)		0.1
Egg plant		0.1
Other solanaceous vegetables		0.1
Cucumber (including gherkin)		0.1
Pumpkin (including squash)	0.1	0.1
Oriental pickling melon (vegetable)	0.03	0.1
Water melon	0.02	0.1
Melons	0.02	0.1
Makuwauri melon	0.1	0.1
Other cucurbitaceous vegetables		0.1
Spinach	0.1	0.1
Bamboo shoots		0.1
Okra		0.1
Ginger		0.1
Peas, immature (with pods)	0.02	0.1
Kidney beans, immature (with pods)	0.05	0.1
Green soybeans		0.1
Button mushroom		0.1
Shiitake mushroom		0.1
Other mushrooms		0.1

Other vegetables	0.02	0.1
Unshu orange, pulp	0.1	0.1
Citrus natsudaidai, whole	2	0.1
Lemon	5	0.1
Orange (including navel orange)	5	0.1
Grapefruit	5	0.1
Lime	5	0.1
Other citrus fruits	5	0.1
Apple	0.1	0.1
Japanese pear	0.1	0.1
Pear	0.1	0.1
Quince		0.1
Loquat		0.1
Peach	0.1	0.1
Nectarine		0.1
Apricot		0.1
Japanese plum (including prune)		0.1
Mume plum	0.02	0.1
Cherry	0.05	0.1
Strawberry		0.1
Raspberry		0.1
Blackberry		0.1
Blueberry		0.1
Cranberry		0.1
Huckleberry		0.1
Other berries		0.1
Grape	0.02	0.1
Japanese persimmon	0.1	0.1
Banana		0.1
Kiwifruit		0.1
Papaya		0.1
Avocado		0.1
Pineapple		0.1
Guava		0.1
Mango		0.1
Passion fruit		0.1
Date		0.1
Other fruits		0.1
Sunflower seeds		0.1
Sesame seeds		0.1
Safflower seeds		0.1
Cotton seeds		0.1
Rapeseeds		0.1
Other oil seeds		0.1

Ginkgo nut		0.1
Chestnut	0.03	0.1
Pecan		0.1
Almond		0.1
Walnut		0.1
Other nuts		0.1
Tea	0.02	0.1
Other spices	10	
Other spices (excluding seeds)		0.1
Other hurbe		0.1
Other dried spices (seeds only)		7

* Shaded figures indicate provisional MRLs.
* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
* In the "Commodity" column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

Notes:
"Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.

"Other legumes/pulses" refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.

"Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.

"Other cruciferous vegetables" refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, *komatsuna* (Japanese mustard spinach), *kyona*, qing-geng-cai, cauliflower, broccoli, and herbs.

"Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.

"Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.

"Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.

"Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.

"Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.

"Other mushrooms" refers to all mushrooms, except button mushroom, and *shiitake* mushroom.

"Other vegetables" refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.

"Other citrus fruits" refers to all citrus fruits, except *unshu* orange (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.

"Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

"Other fruits" refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

"Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

"Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

"Other spices" refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.

"Other herbs" refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

"Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.

"Other poultry animals" refers to all poultry, except chicken.

"Other fish" refers to all fish, except salmoniformes, anguilliformes, and perciformes.

"Other aquatic animals" refers to all aquatic animal, except fish, shelled molluscs and crustaceans.

Item 2. Designation of Food Additives and Revision of Compositional Specifications

Japan is going to designate Potassium Lactate and Potassium Sulfate as authorized additives and to

partially revise the existing compositional specifications for 5-Methylquinoxaline

Under Article 10 of the Food Sanitation Law, 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 law, 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 Potassium Sulfate (CAS No. 7778-80-5) and Potassium Lactate (CAS No. 996-31-6) as food additives as well as the revision of compositional specifications for 5-Methylquinoxaline (CAS No. 13708-12-8). The conclusion of the committee is outlined below.

Potassium Sulfate and Potassium Lactate are widely used abroad as flavoring agent. Main specific uses are flavoring agent or flavoring adjuvant for Potassium Sulfate and flavor enhancer, flavoring agent, flavoring adjuvant and acidity regulator for Potassium Lactate.

Outline of conclusion

The Minister should designate Potassium Sulfate and Potassium Lactate based on Article 10 of the Food Sanitation Law as food additives unlikely to harm human health, and establish compositional specifications for them based on Article 11 of the law. Also, based on Article 11 of the law, the Minister should modify the requirement of specific gravity for 5-Methylquinoxaline. See Attachment 2-1 through 2-3.

<Additional Information>

Progress in the designation procedure of food additives (54 flavorings and 45 non-flavoring 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 2-4).
As of the end of November 2012, 8 of the 54 flavorings were not approved yet and 14 of the 45 non-flavoring additives were unapproved.

Attachment 2-1

Potassium Sulfate
硫酸カリウム

Standard for use

Not established.

Compositional specifications

Substance name Potassium Sulfate

Molecular formula K_2SO_4

Mol. Weight 174.26

Chemical name [CAS number]
Potassium sulfate [7778-80-5]

Content Potassium Sulfate contains not less than 99.0% of potassium sulfate (K_2SO_4).

Description Potassium Sulfate occurs as colorless or white crystals or crystalline powder.

Identification
Potassium Sulfate responds to all tests for Potassium Salt and Sulfate in the Qualitative Tests.

Purity
(1) pH 5.5–8.5 (1.0 g, water 20 ml).
(2) Lead Not more than 2.0 □g/g as Pb.
Test Solution Weigh exactly 5.0 g of Potassium Sulfate in a 100-ml beaker, and dissolve it in 40 ml of diluted hydrochloric acid (1 in 4). Cover the beaker with a watch glass, boil for 5 minutes, and cool. Designate this solution as the sample solution. To the sample solution, add 10 ml of a solution of diammonium hydrogen citrate (1 in 2), and make weekly alkaline with ammonia solution using thymol blue TS as an indicator. After cooling, transfer the resulting solution to a 200-ml separating funnel. Wash the beaker with water and add the washings to the separating funnel to make about 100 ml. Add 5 ml of a solution of ammonium pyrrolidine dithiocarbamate (3 in 100), and allow to stand for 5 minutes. Add 10 ml of butyl acetate, agitate for 5 minutes, and allow to tand. 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 10 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.
(3) Selenium Not more than 30 □g/g.
Test solution and control solution Place 0.20 g of Potassium Sulfate in a beaker, add 25 ml of hydrochloric acid TS (4 mol/L), shake, and add 25 ml of water. Designate this solution as the sample solution.
Measure exactly 3 ml of Selenium Standard Solution, and add water to make exactly 1000 ml. Measure exactly 2 ml o f this solution in a beaker, and add 50 ml of hydrochloric acid TS (2 mol/L). Designate this solution as the control stock solution.
Carefully add 5 ml of ammonia solution to each of the sample solution and control stock solution. Do this step in a draft chamber. After cooling, adjust the pH of each solution to 1.8–2.2 with diluted ammonia solution (1 in 2), and add water to make 60 ml each. Transfer them to separate separating funnels, wash each beaker with 10 ml of water, and add the washings to each separating funnel. Add 0.2 g of hydroxylammonium chloride to each, and dissolve while gently shaking. Add 5 ml of 2,3-diamononaphthalene TS, shake, and allow to stand for 100 minutes. To each, add 5.0 ml of cyclohexane, shake well for 2 minutes. Collect the cyclohexane layers, separately centrifuge at 3000 rmp for10 minutes. Use the upper layers of them as the test solution and control solution, respectively.
Procedure Measure the absorbance of them at the maximum absorption wavelength around 378 nm against a reference that is prepared using 50 ml of hydrochloric acid TS (2 mol/L) in the same manner as for the sample solution. The absorbance of the test solution is not greater than that of the control solution.
(4) Arsenic Not more than 4.0 □g/g as As_2O_3 (0.50 g, Method 1, Apparatus B).

Assay Weigh accurately about 0.5 g of Potassium Sulfate, dissolve it in 200 ml of water, add 1 ml of

hydrochloric acid, and boil. Add 8 ml of barium chloride solution (3 in 25) little by little while stirring, and heat on a water bath for 1 hour. After cooling, filter the solution through a filter paper for quantitative analysis (5C), and wash the residue on the filter paper with water until the washing no longer shows chloride reaction. Place the filter paper with residue in a crucible, already ignited and weighed, dry it, and ignite at 500–600°C to constant weight. Weigh accurately the residue, and calculate the content by the formula:

$$\text{Content (\%) of potassium sulfate } (K_2SO_4) = \frac{\text{Weight (g) of the residue} \times 0.7466}{\text{Weight (g) of the sample}} \times 100$$

Regents and Solutions

Sodium Selenite Na_2SeO_3 A white crystalline powder. Soluble in water.

Content Not less than 97.0%.

Purity (1) Solubility of solution Clear (2.0 g, water 20 ml).

(2) Selenium salt and sulfate Measure exactly 5 ml of the test solution prepared in (1), add 10 ml of water, and adjust the pH to 6.0 with diluted hydrochloric acid (1 in 3). Add 1 ml of diluted hydrochloric acid (2 in 3), and add water to make exactly 25 ml. To the resulting solution, add 2 ml of barium chloride solution (1 in 10), and allow to stand for 30 minutes. The solution is not turbid.

Assay Weigh accurately about 1 g of Sodium Selenium, and dissolve in water to make exactly 200 ml. Transfer exactly measured 20 ml of this solution to a 200-ml iodine flask or a 200-ml Erlenmeyer flask with a ground glass stopper. Add 80 ml of water, 3 g of potassium iodide, and 5 ml of diluted hydrochloride acid (2 in 3). Immediately stopper, allow to stand for 5 minutes in a dark place. Titrate the free iodine with 0.1 mol/L sodium thiosulfate using 0.5 ml of starch TS as the indicator. Separately, perform a blank test to make necessary correction. Starch TS should be added when the color of the solution becomes light yellow near endpoint. The endpoint is when the blue color of solution disappears.

Each ml of 0.1 mol/L sodium thiosulfate = 4.324 mg of Na_2SeO_3

Hydrochloric Acid TS (2 mol/L) Measure 180 ml of hydrochloric acid, and add water to make 1000 ml.

Hydrochloric Acid TS (4 mol/L) Measure 360 ml of hydrochloric acid, and add water to make 1000 ml.

Nitric Acid TS (0.1 mol/L) Measure 6.4 ml, 6.9 ml, or 7.6 ml of nitric acid whose concentration is 69–70%, 65–66%, or 60–61%, whichever is appropriate, and add water to make 1000 ml.

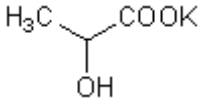
Standard Solutions

Selenium Standard Solution Weigh 2.19 g, add nitric acid TS (0.1 mol/L) to make exactly1000 ml. Each ml of this solution contains 1 mg of selenium (Se).

Attachment 2-2

Potassium Lactate

乳酸カリウム液



Standard for use
Not established.

Compositional specifications
Substance name Potassium Lactate

Molecular formula $C_3H_5KO_3$

Mol. Weight 128.17

Chemical name [CAS number]
Monopotassium 2-hydroxypropanoate [996-31-6]

Content Potassium Lactate contains not less than 50.0% of potassium lactate ($C_3H_5KO_3$) and the equivalent of 95−110% of the labeled content.

Description Potassium Lactate is a colorless, clear, slightly viscose liquid. It is odorless or has a slight characteristic odor.

Identification Potassium Lactate responds to all tests for Potassium Salt and Lactate in the Qualitative Tests.

Purity
Free acid Weigh exactly an amount of Potassium Lactate equivalent to 0.60 g of potassium lactate, add 20 ml of freshly boiled and cooled water and 3 drops of phenolphthalein TS, and titrate with 0.1 mol/L sodium hydroxide. Its consumption is not more than 0.2 ml.

Lead Not more than 2.0 μg/g as Pb for 60% potassium lactate.
Test Solution Weigh an amount of Potassium Lactate equivalent to 3.0 g of potassium lactate, place to a crucible, and add 2 ml of sulfuric acid little by little. Heat gradually at as low temperature as possible until the sample in the crucible is carbonized and white fumes are no longer evolved. Place the crucible in an electric muffle, and ignite at 450−550°C until the sample is calcified. To the residue, add 10 ml of diluted hydrochloric acid (1 in 4), and heat to dryness on a water bath. To the residue, add diluted nitric acid (1 in 150), dissolve by ultrasonic treatment, and add diluted nitric acid (1 in 150) again to make exactly 10 ml.
Control Solution Measure exactly 1 ml of Lead Standard Solution, and add diluted nitric acid (1 in 150) to make exactly 10 ml.
Procedure For the test solution and the control solution, proceed as directed in Method 1 in the Lead Limit Test.

Arsenic Not more than 4.0 μg/g as As_2O_3.
Test Solution Weigh an amount of Potassium Lactate equivalent to 0.60 g of potassium lactate, and add water to make 10 ml. Use 5 ml of this solution as the test solution.
Apparatus Use Apparatus B.

Reducing substances Add 5 drops of Potassium Lactate to 10 ml of Fehling's TS, and boil for 5 minutes. No red precipitate is produced.

Assay Weigh accurately an amount of Potassium Lactate equivalent to about 0.3 g of potassium

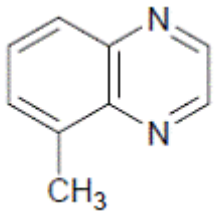
lactate, and evaporate to dryness. To the residue, add 60 ml of a 5:1 mixture of acetic acid/acetic anhydride, dissolve completely, and titrate with 0.1 mol/L perchloric acid. Usually, a potentiometer is used to confirm the endpoint. When crystal violet-acetic acid TS (1 ml) is used as the indicator, the endpoint is when the color of the solution changes from violet through blue to green. Separately perform a blank test to make necessary correction.

Each ml of 0.1 mol/L perchloric acid = 12.82 mg of $C_3H_5KO_3$

Attachment 2-3

5-Methylquinoxaline

5-メチルキノキサリン



Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 5-Methylquinoxaline

Molecular formula $C_9H_8N_2$

Mol. Weight 144.17

Chemical name [CAS number]

5-Methylquinoxaline [13708-12-8]

Content 5-Methylquinoxaline contains not less than 98.0% of 5-methylquinoxaline ($C_9H_8N_2$).

Description 5-Methylquinoxaline occurs as a colorless to orange-color liquid or crystalline lumps having a characteristic odor.

Identification Determine the infrared absorption spectrum of 5-Methylquinoxaline as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

Purity

(1) Refractive index n_D^{20} : 1.615–1.625.

(2) Specific gravity d_{20}^{20}: ~~1.102–1.128~~. 1.102–1.132.

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