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Japan

Food and Agricultural Import Regulations and Standards

Designation of food additives - Isovaleraldehyde, and two other chemicals

2008

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Report Highlights:

On July 28, 2008, the Japanese Government announced the planned approval of the food additives, Isovaleraldehyde, Sodium stearoyl-2-lactylate and Valeraldehyde. The comment period will close on August 11, 2008.

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

Summary

On July 28, 2008. The Japanese Ministry of Health Labour and Welfare (MHLW) announced the planned approval of the food additives, Isovaleraldehyde, Sodium stearoyl-2-lactylate and Valeraldehyde. The period for sending comments on these changes ends August 11. 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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Designation of Food Additives

Purpose and background

Ministry of Health, Labour and Welfare is going to newly designate substances listed below as authorized food additives.

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 not permitted to be used or marketed unless they meet these standards or specifications.

In 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 the substances.

The subcommittee has concluded as follows.

<Food additives to be designated>
Sodium stearoyl lactylate
Isovalealdehyde, Valealdehyde

Outline of conclusion

The Minister should designate Sodium Stearoyl Lactylate, Isovalealdehyde, and Valealdehyde, based on Article 10 of the Food Sanitation Law, as a food additive unlikely to harm human health and establish compositional specifications for them, based on Article 11 of the law (see Attachments 2-1, 2-2, and 2-3).

Additional Information

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 2-4)

Attachment 2-1

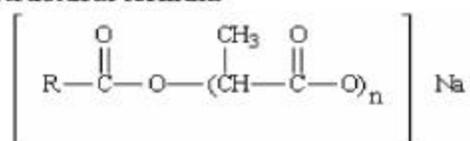
Sodium Stearoyl-2-lactylate**Sodium Stearoyl Lactylate****Standard for use**

See the Appendix.

Compositional specifications

Substance name Sodium Stearoyl-2-lactylate

Structural formula



*The lactic acid may contain its dextrorotatory form and racemic form.

Molecular formula and molecular weight of major components

$\text{C}_{21}\text{H}_{39}\text{O}_4\text{Na}$ (R-CO: stearoyl group $\text{CH}_3(\text{CH}_2)_{16}$, n=1) Mol. Wt. 378.53

$\text{C}_{24}\text{H}_{43}\text{O}_4\text{Na}$ (R-CO: stearoyl group $\text{CH}_3(\text{CH}_2)_{16}$, n=2) Mol. Wt. 450.59

$\text{C}_{19}\text{H}_{35}\text{O}_4\text{Na}$ (R-CO: palmitoyl group $\text{CH}_3(\text{CH}_2)_{14}$, n=1) Mol. Wt. 350.47

Chemical name, CAS number

Monosodium 2-(octadecanoyloxy)propanoate [25383-99-7]

Monosodium 2-[[2-(octadecanoyloxy)propanpyloxy]propanoate [25383-99-7]

Monosodium 2-(hexadecanoyloxy)propanoate [617-57-2]

Definition Sodium Stearoyl-2-lactylate is a mixture of sodium salts of stearoyl lactic acids as major components and minor proportions of related acids and other salts of these acids.

Description It occurs as a white to slightly yellowish powder or brittle solid with a characteristic odor.

Identification

(1) Add 10 ml of diluted hydrochloric acid (1 in 4) to 2 g of Sodium Stearoyl-2-lactylate, heat in a water bath for 5 minutes, and filter. The filtrate imparts a yellow color to the flame. Next, neutralize the filtrate and add potassium hydrogen pyroantimonate TS. A white crystalline precipitate is formed.

(2) To the residue obtained by filtration in test (1), add 30 ml of sodium hydroxide (1 in 25), and heat while stirring for 30 minutes in a water bath at a temperature of not less than 95°C. After cooling, add 20 ml of diluted hydrochloric acid (1 in 4). Extract twice from the mixture with two 30 ml portions of diethyl ether, and combine the

diethyl ether layers, and wash with 20 ml of water. Add anhydrous sodium sulfate to dehydrate, and filter. Heat the filtrate on a water bath to completely evaporate the diethyl ether. The melting point of the residue is 54–60°C.

(8) Sodium Stearoyl-2-lactylate responds to the test for Lactate in the Qualitative Tests.

Purity

(1) Acid value 60–130.

Weigh accurately about 1 g of Sodium Stearoyl-2-lactylate, add 25 ml of neutralized ethanol, and dissolve while warming. After cooling, add 3 drops of phenolphthalein TS, and immediately titrate with 0.1 mol/L sodium hydroxide to the first faint pink that persists for 30 seconds. Calculate the acid value by the formula

$$\text{Acid value} = \frac{\text{Volume (ml) of 0.1 mol/L sodium hydroxide consumed} \times 5.611}{\text{Weight (g) of the sample}}$$

(2) Ester value 90–100 (Fats and Related Substances Tests).

To determine the ester value, use the acid value calculated in (1). To determine the saponification value, proceed as directed in Saponification Value under the Fats and Related Substances Tests, using 1 g of Sodium Stearoyl-2-lactylate, accurately weighed. When adding ethanolic potassium hydroxide TS, be careful not to let the deposits produced adhere to the wall of the flask. Titration should be performed while hot.

(3) Total lactic acid 15–40% as lactic acid (C₃H₅O₃).

Proceed as directed in Purity (3) for Calcium Stearoyl Lactylate. To prepare a calibration curve, use 1, 2, 5, and 10 ml of Lithium Lactate Standard Solution, respectively.

(4) Sodium 2.5–3.0%.

Test Solution Place about 0.25 g of Sodium Stearoyl-2-lactylate, accurately weighed, into a beaker, add 10 ml of ethanol, and dissolve while warming. Transfer this solution into a 25-ml volumetric flask, wash the beaker twice with two 5 ml portions of ethanol, and add the washings to the flask. Make up to volume with ethanol, and mix well. Transfer exactly 1 ml of the resulting solution into a 100-ml volumetric flask containing 10 ml of lanthanum oxide TS, make up to volume with water, and filter through a 50 filter paper.

Standard Solutions Dissolve 1.271 g of sodium chloride, dried at 130°C for 2 hours and exactly weighed, in water to make exactly 500 ml. To exactly 10 ml of this solution, add water to make a standard stock solution of exactly 100 ml (0.1 mg/ml Na). Place exactly 1, 2, 4, and 6 ml of the stock standard solution into separate 100-ml volumetric flasks, add 10 ml of lanthanum oxide TS to each, and dilute to volume with water. These solutions contain 2, 4, and 6 µg of sodium (Na=22.99) per ml, respectively. Prepare standard solutions fresh. Perform the test by the Flame Method in Atomic Absorption Spectrophotometry, using the operating conditions given below. Prepare a calibration curve using the standard solutions to determine the sodium concentration, and calculate the sodium content by the formula

$$\text{Sodium content(\%)} = \frac{\text{Concentration } (\mu\text{g/ml of sodium})}{\text{Weight(g) of the sample} \times 4}$$

Operating Conditions

Light source: Sodium hollow cathode lamp

Wavelength: 589.0 nm

Supporting gas: Air

Combustible gas: Acetylene

(5) Lead Not more than 2.0 $\mu\text{g/g}$ as Pb (5.0 g. Method 1).

(6) Arsenic Not more than 4.0 $\mu\text{g/g}$ as As_2O_3 .

<Reagents>

Lanthanum Oxide (III) La_2O_3 White crystals.

Loss on Ignition Not more than 0.5% (1 g, 100°C, 1 hour).

Lanthanum Oxide TS Place 5.86 g of Lanthanum Oxide (III) into a 100-ml volumetric flask, add 2 to 3 ml of water to moisten, and slowly add 25 ml of hydrochloric acid. Shake to dissolve completely, and make up to volume with water.

Appendix

Standards for use

Target Food	Maximum Limit (g/kg)	Limitation for Use
Bread.	4.0	
Butter cakes.	5.5	
Confections (baked or fried wheat flour products only, excluding sponge cakes and butter cakes).	4.0	
Moist cakes (rice flour products only).	6.0	
Macaroni and other such products.	4.0 *	*per kg of dry noodles.
Mixed powder for manufacturing:		
Bread.	5.5	
Confections (fried wheat flour products only).	5.5	
Confections (baked wheat flour products only, excluding sponge cakes and butter cakes).	5.0	
Moist cakes.	10	
Sponge cakes, butter cakes and steamed breads.	8.0	
Steamed MANJYU (bun made by steaming wheat flour dough).	2.5	
Noodles (raw noodles and instant noodles, excluding other dry noodles).	4.5 **	**per kg of boiled noodles.
Sponge cakes.	5.5	
Steamed bread (bread made by steaming wheat flour dough).	5.5	
Steamed MANJYU	2.0	

Attachment 2-2

Isovaleraldehyde
3-Methylbutyraldehyde
3-Methylbutanal

Standard for use

It must not be used for purposes other than flavoring.

Compositional specifications

Substance name Isovaleraldehyde

Structural formula



Molecular formula C₅H₁₀O

Mol. Weight 86.13

Chemical name, CAS number 3-Methylbutanal [590-86-3]

Content Isovaleraldehyde contains not less than 95.0% of butyraldehyde (C₅H₁₀O).

Description Isovaleraldehyde occurs as a colorless to light yellow liquid, having a characteristic odor.

Identification Determine the infrared absorption spectrum of Isovaleraldehyde, 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 wave numbers.

Purity

(1) **Refractive index** n_D^{20} : 1.387–1.408.

(2) **Specific gravity** d_{25}^{25} : 0.795–0.815

(3) **Acid value** Not more than 10.0 (Flavoring Substance Tests).

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

Attachment 2-3

Valeraldehyde
Pentanal

Standard for use

It must not be used for purposes other than flavoring.

Compositional specifications

Substance name Valeraldehyde

Structural formula

Molecular formula $\text{C}_5\text{H}_{10}\text{O}$

Mol. Weight 86.13

Chemical name, CAS number Pentanal [110-62-3]

Content Valeraldehyde contains not less than 95.0% of butyraldehyde ($\text{C}_4\text{H}_8\text{O}$).

Description Valeraldehyde occurs as a colorless to light yellow liquid, having a characteristic odor.

Identification Determine the infrared absorption spectrum of Valeraldehyde, 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 wave numbers.

Purity

(1) Refractive index n_D^{20} : 1.390-1.400.(2) Specific gravity d_4^{20} : 0.805-0.820

(3) Acid value Not more than 5.0 (Flavoring Substance Tests).

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (5).