Date: 4/8/2019
GAIN Report Number: JA9035

Japan

Post: Tokyo

Japan Proposes Designation of 7 New Food Additives

Report Categories:
Sanitary/Phytosanitary/Food Safety
WTO Notifications
Approved By:
Jess K. Paulson
Prepared By:
Tomohiro Kurai

Report Highlights:
On March 18, 2019, Japan notified the World Trade Organization (WTO) of a proposal to designate Isobutylamine, Isopropylamine, sec-Butylamine, Propylamine, Hexylamine, Pentylamine and 2-Methylbutylamine as food additives via G/SPS/N/JPN/623. Japan will not establish a public comment period for this proposal as it relaxes the regulation. However, interested U.S. parties are welcome to share their comments and/or concerns with USDA's enquiry point (us.spsenquirypoint@fas.usda.gov).

Keywords: JA9035, food additive, Argon, Isobutylamine, Isopropylamine, sec-Butylamine, Propylamine, Hexylamine, Pentylamine, 2-Methylbutylamine

General Information:

On March 18, 2019, Japan notified the World Trade Organization (WTO) of a proposal to designate Isobutylamine, Isopropylamine, sec-Butylamine, Propylamine, Hexylamine, Pentylamine and 2-Methylbutylamine as food additives via G/SPS/N/JPN/623. In the notification, the Ministry of Health, Labour and Welfare (MHLW), the regulatory agency responsible for food safety in Japan, designates these chemicals as food additives and specifies Annex 1 below as standards for use of these chemicals as food additives. This proposal will take an immediate effect once the official Japanese Governmental Gazette is published.

There will be no public comment period established for this proposal as it relaxes the regulation. However, interested U.S. parties are welcomed to share their comments and/or concerns with USDA's enquiry point (us.spsenquirypoint@fas.usda.gov).

(The following is taken from Japan's notification)

Annex 1 – Amendment to the Ordinance for Enforcement of the Food Sanitation Act and the Specifications and Standards for Foods, Food Additives, Etc.

The government of Japan will designate Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine, and 2-Methylbutylamine as authorized food additives and establish the standards for use and the compositional specifications.

Summary

The Food Sanitation Act (hereinafter referred to as "the Act"), in Article 10, prohibits the use and the sale of the food additives the Minister of Health, Labour and Welfare (hereinafter referred to as "the Minister") does not designate. In addition, when specifications or standards for food additives are stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Ministry of Health and Welfare Notification No. 370, 1959) pursuant to Article 11 of the Act, those additives shall not be used or sold unless they meet the standards or the specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Committee") has discussed the adequacy of the designation of Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine, and 2-Methylbutylamine as food additives. The conclusion of the Committee is outlined below.

Outline of conclusion

The Minister, pursuant to Article 10 of the Act, should designate Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine, and 2-Methylbutylamine as food additives unlikely to harm human health and establish the standards for use and the compositional specifications pursuant to Article 11 of the Act (see Attachment for the details).

Attachment

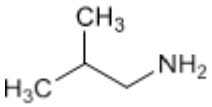
Isobutylamine
イソブチルアミン

Standard for use (draft)

Only for flavoring Compositional

specifications (draft)

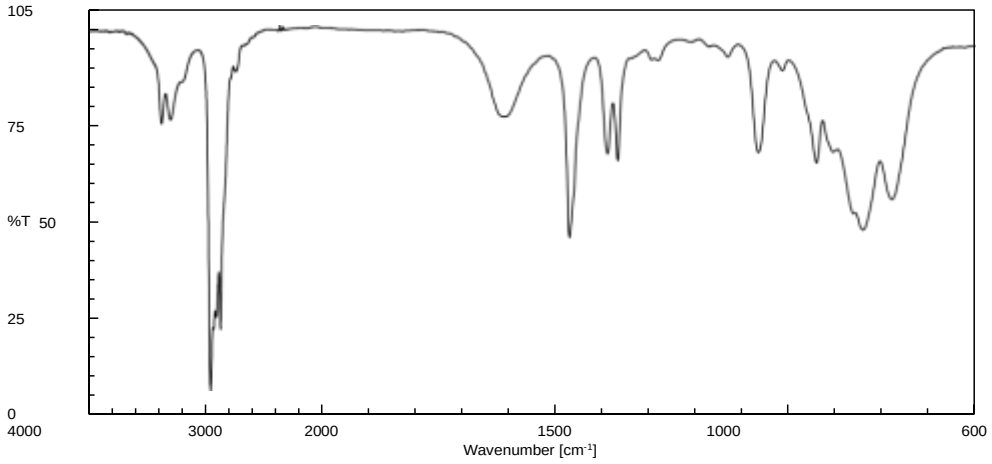
Substance name Isobutylamine
Structural formula



Molecular formula $C_4H_{11}N$
Molecular weight 73.14
Chemical name [CAS number] 2-Methylpropan-1-amine [78-81-9]
Content Isobutylamine contains not less than 95.0% of isobutylamine ($C_4H_{11}N$).
Description Isobutylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of Isobutylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}: 1.391–1.400
Specific gravity d_{25}^{25}: 0.724–0.737
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30– 60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

Isobutylamine



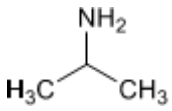
Isopropylamine
イソプロピルアミン

Standard for use (draft)

Only for flavoring **Compositional**

specifications (draft)

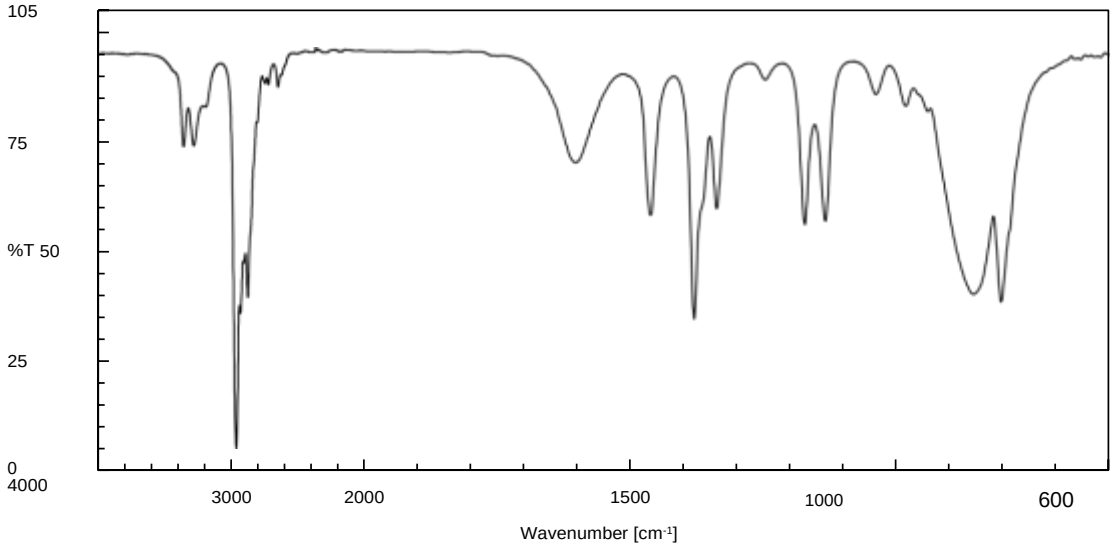
Substance name Isopropylamine
Structural formula



Molecular formula C_3H_9N **Molecular weight** 59.11
Chemical name [CAS number] Propan-2-amine [75-31-0]
Content Isopropylamine contains not less than 95.0% of isopropylamine (C_3H_9N).
Description Isopropylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of Isopropylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}: 1.367–1.378
Specific gravity d_{25}^{25}: 0.681–0.693
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

Isopropylamine



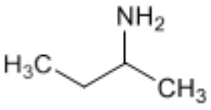
sec-Butylamine
sec-ブチルアミン

Standard for use (draft)

Only for flavoring **Compositional**

specifications (draft)

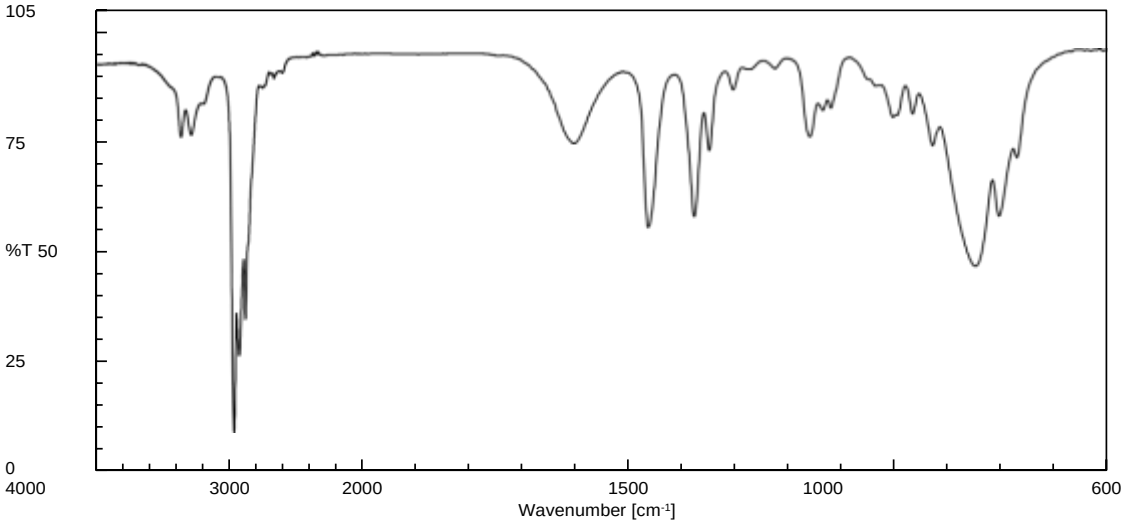
Substance name *sec*-Butylamine
Structural formula



Molecular formula $C_4H_{11}N$
Molecular weight 73.14
Chemical name [CAS number] Butan-2-amine [13952-84-6]
Content *sec*-Butylamine contains not less than 95.0% of *sec*-butylamine ($C_4H_{11}N$).
Description *sec*-Butylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of *sec*-Butylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}: 1.387–1.396
Specific gravity d_{25}^{25}: 0.715–0.724
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

sec-Butylamine



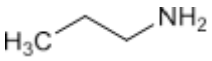
Propylamine
プロピルアミン

Standard for use (draft)

Only for flavoring Compositional

specifications (draft)

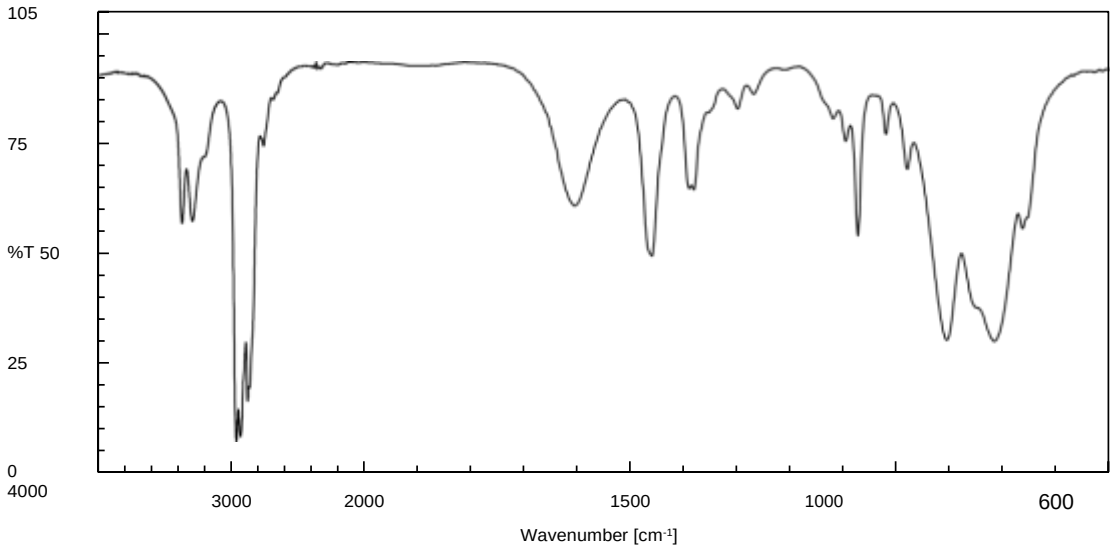
Substance name Propylamine
Structural formula



Molecular formula C_3H_9N **Molecular weight** 59.11
Chemical name [CAS number] Propan-1-amine [107-10-8]
Content Propylamine contains not less than 95.0% of propylamine (C_3H_9N).
Description Propylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of Propylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}: 1.384–1.392
Specific gravity d_{25}^{25}: 0.710–0.720
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

Propylamine



Hexylamine
ヘキシルアミン

Standard for use (draft)

Only for flavoring Compositional

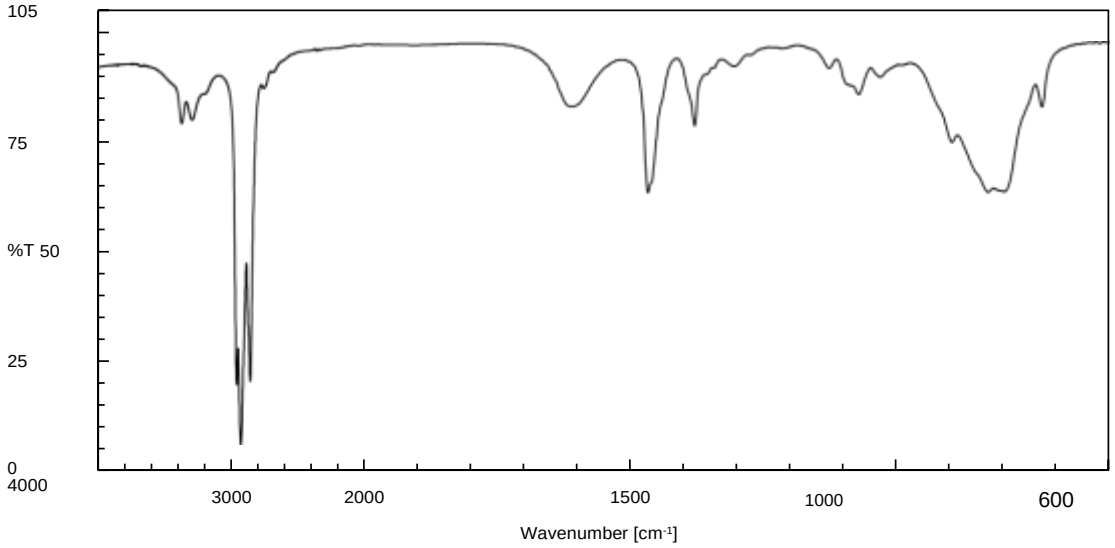
specifications (draft)

Substance name Hexylamine
Structural formula

Molecular formula $C_6H_{15}N$
Molecular weight 101.19
Chemical name [CAS number] Hexan-1-amine [111-26-2]
Content Hexylamine contains not less than 95.0% of hexylamine ($C_6H_{15}N$).
Description Hexylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of Hexylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}:1.415–1.421
Specific gravity d_{25}^{25}: 0.761–0.767
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

Hexylamine



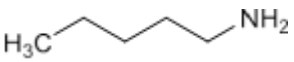
Pentylamine
ペンチルアミン

Standard for use (draft)

Only for flavoring Compositional

specifications (draft)

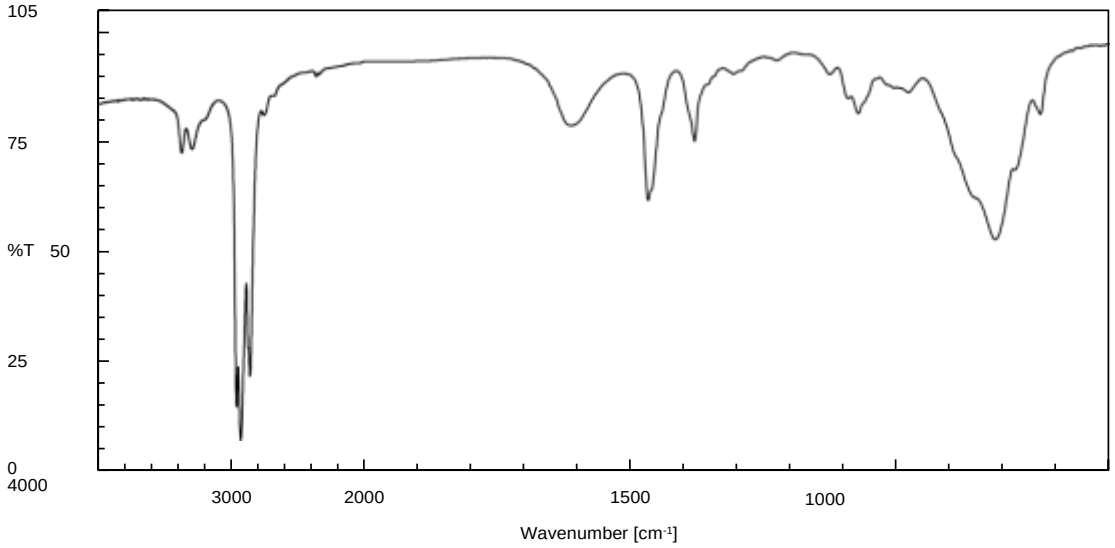
Substance name Pentylamine
Structural formula



Molecular formula $C_5H_{13}N$
Molecular weight 87.16
Chemical name [CAS number] Pentan-1-amine [110-58-7]
Content Pentylamine contains not less than 95.0% of pentylamine ($C_5H_{13}N$).
Description Pentylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of Pentylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}: 1.408–1.424
Specific gravity d_{25}^{25}: 0.750–0.759
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

Pentylamine



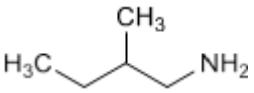
2-Methylbutylamine
2-メチルブチルアミン

Standard for use (draft)

Only for flavoring Compositional

specifications (draft)

Substance name 2-Methylbutylamine **Structural formula**



Molecular formula $C_5H_{13}N$
Molecular weight 87.16
Chemical name [CAS number] 2-Methylbutan-1-amine [96-15-1]
Content 2-Methylbutylamine contains not less than 95.0% of 2-methylbutylamine ($C_5H_{13}N$).
Description 2-Methylbutylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.
Identification Determine the infrared absorption spectrum of 2-Methylbutylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.
Refractive index n_D^{20}: 1.408–1.423
Specific gravity d_{25}^{25}: 0.752–0.779
Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference spectrum

2-Methylbutylamine