

Approval/authorization for use of piperidine and pyrrolidine as food additives

Purpose and background

This activity is to newly designate piperidine and pyrrolidine as authorized food additives.

Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only when they are authorized by the Minister of Health, Labour and Welfare. Where standards for use of additives and/or their compositional specifications are established based on Article 11 of the law, those additives may be used or marketed only when they meet the standards and/or specifications.

In response to a request from the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee which is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of designation of the two substances, i.e. piperidine and pyrrolidine, as food additives. Conclusion of the subcommittee is outlined below.

Outline of conclusion

The Minister should designate piperidine and pyrrolidine, based on Article 10 of the Food Sanitation Law, as food additives unlikely to harm human health, and establish compositional specifications and other necessary standards for these substances, based on Article 11 of the law (see Attachments 1 and 2).

Attachment 1

Piperidine

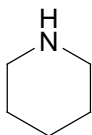
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name: Piperidine

Structural formula:



Molecular formula: C₅H₁₁N

Mol. Weight: 85.15

Chemical name [CAS number]: Piperidine [110-89-4]

Content: Piperidine contains not less than 98.0% of piperidine (C₅H₁₁N).

Description: Piperidine occurs as a colorless to light yellow, transparent liquid having a characteristic odor.

Identification: Determine the infrared absorption spectrum of Piperidine, 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:

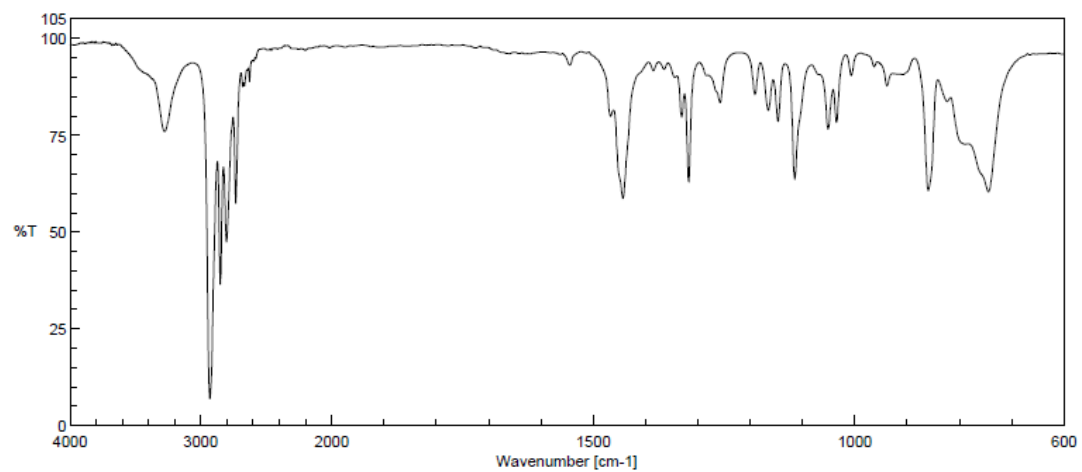
(1) Refractive index n_D^{20} : 1.450–1.454.

(2) Specific gravity d_{25}^{25} : 0.858–0.862.

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

Reference Spectrum

Piperidine



Attachment 2

Pyrrolidine

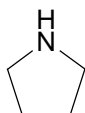
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name: Pyrrolidine

Structural formula:



Molecular formula: C₄H₉N

Mol. Weight: 71.12

Chemical name [CAS number]: Pyrrolidine [123-75-1]

Content: Pyrrolidine contains not less than 95.0% of pyrrolidine (C₄H₉N).

Description: Pyrrolidine occurs as a colorless, transparent liquid having a characteristic odor.

Identification: Determine the infrared absorption spectrum of Pyrrolidine, 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} : 1.440–1.446.

(2) Specific gravity d_{25}^{25} : 0.853–0.863.

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests, using operating conditions (2). Use a silicate glass capillary column (0.25–0.53 mm in internal diameter and 30–60 m in length), coated with a 0.25–1 μm thick layer of dimethyl polysiloxane.

Reference Spectrum

Pyrrolidine

