Assay Not less than 98.5% and not more than 101.5% of $C_9H_{11}NO_3$, calculated on the dried basis.
Lead Not more than 5 mg/kg.
Loss on Drying Not more than 0.3%.
Optical (Specific) Rotation $[\alpha]_D^{20°}$: Between −11.3° and −12.3°, calculated on the dried basis; or $[\alpha]_D^{25°}$: Between −10.0° and −11.0°, calculated on the dried basis.
Residue on Ignition Not more than 0.1%.

TESTS

Assay Transfer about 400 mg of sample, previously dried at 105° for 3 h and accurately weighed, into a 250-mL flask. Dissolve the sample in about 50 mL of glacial acetic acid, add 2 drops of crystal violet TS, and titrate with 0.1 *N* perchloric acid to a blue-green endpoint.

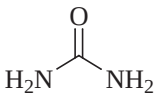
> **Caution**: Handle perchloric acid in an appropriate fume hood.

Perform a blank determination (see *General Provisions*), and make any necessary correction. Each milliliter of 0.1 *N* perchloric acid is equivalent to 18.12 mg of $C_9H_{11}NO_3$.
Lead Determine as directed under *Lead Limit Test*, Appendix IIIB, using a *Sample Solution* prepared as directed for organic compounds, and 5 μg of lead (Pb) ion in the control.
Loss on Drying Determine as directed under *Loss on Drying*, Appendix IIC, drying a sample at 105° for 3 h.
Optical (Specific) Rotation Determine as directed under *Optical (Specific) Rotation*, Appendix IIB, using a solution containing 5 g of a previously dried sample in sufficient 1 *N* hydrochloric acid to make 100 mL.
Residue on Ignition Determine as directed under *Residue on Ignition*, Appendix IIC, igniting a 2-g sample.

Packaging and Storage Store in well-closed containers.

Urea

Carbamide



CH_4N_2O Formula wt 60.06

CAS: [57-13-6]

DESCRIPTION

Urea occurs as a colorless to white, prismatic, crystalline powder or as small, white pellets. It is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis. It is freely soluble in water and in boiling alcohol, but practically insoluble in chloroform and in ether. It melts at a range of 132° to 135°.

Function Fermentation aid.

REQUIREMENTS

Identification

A. Heat about 500 mg of sample in a test tube until it liquefies. Ammonia vapor is produced. Continue heating until the liquid becomes turbid, and then cool. Dissolve the fused mass in a 1:10 sodium hydroxide solution:water mixture. Add 1 drop of cupric sulfate TS. A red-violet colored solution develops.

B. Dissolve 100 mg of sample in 1 mL of water, and add 1 mL of nitric acid. A white precipitate of urea nitrate forms.
Assay Not less than 99.0% and not more than 100.5% of CH_4N_2O.
Alcohol-Insoluble Matter Not more than 0.04%.
Chloride Not more than 0.007%.
Lead Not more than 5 mg/kg.
Loss on Drying Not more than 1.0%.
Residue on Ignition Not more than 0.1%.
Sulfate Not more than 0.01%.

TESTS

Assay Transfer about 500 mg of sample, accurately weighed, into a 200-mL volumetric flask, and dissolve it in 100 mL of water, dilute to volume with water, and mix. Pipet 2 mL of this solution into a semimicro Kjeldahl digestion flask, and proceed as directed in *Method II* under *Nitrogen Determination*, Appendix IIIC. Heat the sample until it begins to fume, and then heat for 1 additional hour. Each milliliter of 0.01 *N* acid is equivalent to 0.3003 mg of CH_4N_2O.
Alcohol-Insoluble Matter Dissolve about 5 g of sample, accurately weighed, in 50 mL of warm alcohol. If any residue remains, filter the solution through a tared filter, wash the residue, and filter with 20 mL of warm alcohol. Dry at 105° for 1 h. Cool in a desiccator, and weigh.
Chloride Determine as directed in the *Chloride Limit Test* under *Chloride and Sulfate Limit Tests*, Appendix IIIB, using 0.2 g of sample, and 14 μg of chloride (Cl) ion in the control.
Lead Determine as directed under *Lead Limit Test*, Appendix IIIB, using 2 g of sample, and 10 μg of lead (Pb) ion in the control.
Loss on Drying Determine as directed under *Loss on Drying*, Appendix IIC, drying a sample at 105° for 3 h.
Residue on Ignition Determine as directed in *Method I* under *Residue on Ignition*, Appendix IIC, igniting a 1-g sample.
Sulfate Determine as directed in the *Sulfate Limit Test* under *Chloride and Sulfate Limit Tests*, Appendix IIIB, using 2 g of sample, and 200 μg of sulfate (SO_4) ion in the control.

Packaging and Storage Store in a well-closed container.