

# UREA

*Prepared at the 41st JECFA (1993), published in FNP 52 Add 2 (1993). Metals and arsenic specifications revised at the 63rd JECFA (2004). Use level of up to 3% in chewing gum, of no toxicological concern, at 41<sup>st</sup> JECFA (1993)*

**SYNONYMS** Carbamide

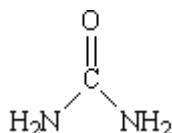
## DEFINITION

Chemical names Urea

C.A.S. number 57-13-6

Chemical formula  $\text{CH}_4\text{N}_2\text{O}$

Structural formula



Formula weight 60.06

Assay Not less than 99.0% and not more than 101.0% on the dried basis

**DESCRIPTION** Colourless or white small pellets or crystalline powder.

**FUNCTIONAL USES** Texturizer in chewing gum, yeast food

## CHARACTERISTICS

### IDENTIFICATION

Solubility (Vol. 4) Very soluble in water; soluble in ethanol

Precipitate formation Dissolve 0.1 g of the sample in water. Add 1 ml of concentrated nitric acid. A white, crystalline precipitate is formed.

Colour reaction Heat 1 g of the sample in a test tube until it liquefies and the liquid becomes turbid. Cool, dissolve in a mixture of 10 ml water and 1 ml of 2 N sodium hydroxide and add 0.05 ml of cupric sulfate TS. A reddish-violet colour is produced.

Melting range (Vol. 4) 132° - 135°

### PURITY

Loss on drying (Vol. 4) Not more than 1.0% (105°, 1 h)

Sulfated ash (Vol. 4) Not more than 0.1%

Ethanol-insoluble matter Not more than 0.04%  
Dissolve 5.0 g of the sample in 50 ml of warm ethanol. Filter the solution on a tared filter, wash the filter with 20 ml of warm ethanol and dry at 105° for 1

h. Cool in a desiccator and weigh. The difference between the total weight and the weight of the filter is the weight of the ethanol-insoluble matter. Calculate the percentage.

Alkalinity

To 10 ml of a 5.0% solution of the sample add 0.1 ml of methyl red TS and 0.4 ml of 0.01 N hydrochloric acid. The resulting solution is red to orange.

Ammonium ion

Not more than 500 mg/kg

Mix 0.1 ml of a 20% solution of the sample with 14 ml of water in a test tube, make alkaline if necessary by the addition of dilute sodium hydroxide TS and dilute to 15 ml with water. To the solution add 0.3 ml of alkaline potassium tetraiodomercurate solution (dissolve 11 g potassium iodide and 15 g of mercuric iodide in water and dilute to 100 ml. Immediately before use, mix 1 volume of this solution with an equal volume of a 25% solution of sodium hydroxide). Prepare a standard by mixing 10 ml of ammonium-ion solution (1 mg  $\text{NH}_4^+$ /l) with water and add 0.3 ml of alkaline potassium tetraiodomercurate solution. Stopper the test tubes. After 5 min, any yellow colour in the test solution is not more intense than in the standard.

Biuret

Not more than 0.1%

To 10 ml of a 20% solution of the sample add 5 ml water, 0.5 ml of a 0.5 % w/v solution of cupric sulfate and 0.5 ml of 10 N sodium hydroxide. Allow to stand for 5 min. Any reddish-violet colour in the solution is not more intense than that in a standard prepared at the same time in the same manner using 10 ml of a 0.02% w/v of biuret in place of the sample solution being examined.

Lead (Vol. 4)

Not more than 2 mg/kg

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, "Instrumental Methods."

**METHOD OF ASSAY**

Accurately weigh about 0.5 g of the sample and dissolve in a 10% sulfuric acid solution and dilute to 100 ml with the same acid. Introduce 5.0 ml of this solution into a long-necked combustion flask, add 10 ml of sulfuric acid TS and heat gently until gas is no longer evolved. Boil gently for 10 min, cool and add cautiously 40 ml of water. Cool again and place in a steam-distillation apparatus. Add 50 ml of 10 N sodium hydroxide solution and distil immediately by passing steam through the mixture. Distil for 1 hour, collecting about 50 ml of distillate in 40 ml of a 4% w/v solution of boric acid. Add 0.25 ml of methyl red/methylene blue TS and titrate with 0.1 N hydrochloric acid. Carry out a blank determination. Each ml of 0.1 N hydrochloric acid is equivalent to 3.003 mg of  $\text{CH}_4\text{N}_2\text{O}$ .