U. S. Department of Commerce Frederick B. Dent Secretary

National Bureau of Standards and W. Ruberts, Director

National Bureau of Standards Certificate of Analysis Standard Reference Material 912

UREA

This Standard Reference Material is certified as a chemical of known purity. It is intended primarily for use in the calibration and standardization of procedures for urea nitrogen determinations employed in clinical analysis and for routine critical evaluation of daily working standards used in these procedures.

Purity	 . 99.7 percent
Moisture	 . 0.18 percent
Biuret	 . 0.07 percent
Ash	 . 0.002 percent
Insoluble matter	

The value of the purity has an estimated inaccuracy of 0.1 percent.

The urea used for this Standard Reference Material was obtained from the Mann Research Laboratories of New York, N.Y. Analyses were performed by D. A. Becker, R. F. Brady, Jr., B. Coxon, M. M. Darr, T. E. Gills, R. A. Paulson, W. P. Schmidt, J. Thomas, and D. W. Vomhof of the Analytical Chemistry Division.

The overall direction and coordination of technical measurements leading to the certification were under the chairmanship of R. Schaffer.

The technical and support aspects concerning the preparation, certification, and issuance of this Standard Reference Material were coordinated through the Office of Standard Reference Materials by T. W. Mears.

Washington, D. C. 20234 September 24, 1968 Revised November 18, 1970 Revised November 21, 1973 J. Paul Cali, Chief Office of Standard Reference Materials

(over)

A satisfactory method for drying this Standard Reference Material was not found. Either incomplete drying, or excessive (and progressive) weight loss occurred, depending on the degree and intensity of heating and evacuation. However, it was found that this material showed little tendency to gain or lose weight (±0.003 percent) when exposed to laboratory air for a two—week period. Hence, the analyses were performed on this Standard Reference Urea without attempting to lower its moisture content. It is recommended that, after the withdrawal of portions of the Standard Reference Material, the container should be tightly closed. Thus protected, it may be assumed that the moisture content of the Standard Reference Material will remain unchanged. The reported moisture content was determined by the Karl Fischer titration method.

The apparent purity of this Standard Reference Material was determined by two methods. Differential scanning calorimetry [1], performed with a Perkin–Elmer model DSC–1B* instrument on the urea heated through its melting transition, indicated an apparent purity of 99.82 ± 0.03 mole percent. Phase-solubility analysis[2] of the urea in isopropyl alcohol indicated an apparent purity of 99.82 weight percent. These values are designated as "apparent purity", because neither method accounted for the moisture content of the urea. Biuret was estimated spectrophotometrically by use of 50 percent (wt/vol) solutions of urea in aqueous alkaline cupric sulfate measured at its absorption maximum near 560 nm. Measured in a 2-cm cell, a 50 percent (wt/vol) solution of urea in water showed a very strong absorption below 220 nm, a weak absorption (0.10 \pm 0.03) at 280 nm, and a very weak absorption (0.02 \pm 0.01) at 560 nm.

Neither paper nor thin—layer chromatography indicate any evidence of biuret or cyanuric acid. Neither infrared absorption nor nuclear magnetic resonance spectroscopy reveal any unexpected peaks and, hence, they give no evidence of impurity.

The melting range of this Standard Reference Material was 131.5 to 132.4 °C when measured in an open capillary tube heated at 0.5 °C/min.

A 10 percent (wt/vol) solution of this Standard Reference Material in water free from carbon dioxide showed a pH of 7.0 \pm 0.1 at 20 °C.

An emission spectrometric analysis for metallic constituents in the ash from this Standard Reference Material showed the following present as major constituents: aluminum, silicon, iron, sodium, nickel, calcium, magnesium, and manganese.

Neutron activation analysis of the bulk Standard Reference Material indicated the presence of the following approximate concentrations of elements: aluminum, 0.9 ppm; chlorine, less than 1 ppm; copper, 0.27 ppm; gold, 0.0001 ppm; manganese, 0.008 ppm; sodium, 9 ppm; zinc, 0.24 ppm.

*Note - The use of proprietary designations in this certificate is for information only, and should not be construed as an endorsement of the product by either the Department of Commerce or the National Bureau of Standards.

This Standard Reference Material is intended for "in vitro" diagnostic use only.

This material is intended for use as a standard in clinical chemistry. A standard solution containing 20 mg per 100 ml (0.2 mg per ml) of urea nitrogen may be prepared by weighing 0.429 g urea into a one-liter volumetric flask and making to volume with ammonia-free distilled water. A few drops of ACS Reagent-Grade chloroform is added as a preservative. Store in refrigerator [3]. The concentration of urea nitrogen in this solution is approximately that of the normal level in serum. An alternate procedure [4] recommends 0.1 g sodium azide per 100 ml of solution as a preservative.

This Standard Reference Material should be stored in a well-stoppered container at room temperature (30 °C or less). It should not be subjected to heat, moisture or direct sunlight during storage. Refrigerated storage is recommended, but material should be allowed to warm to room temperature before opening the container. Under proper storage, experience at NBS indicates this material to be stable for at least 5 years. If the material purity degrades beyond the limits certified, purchasers will be notified by NBS. It is recommended that this material not be used after 5 years from the date of purchase.

The standard urea nitrogen solution (20mg/100 ml), prepared as described above, is stable for 3 months when stored in a refrigerator at 4 °C and in a well-stoppered, all-glass container.

All constituted solutions of urea should be clear and without indications of bacterial growth of any kind.

References:

- [1] Plato, C. and Glasgow, A. R., Jr., Anal. Chem. 41, 330(1969).
- [2] Mader, W. J., "Phase Solubility in Organic Analysis" in Organic Analysis, Vol II, Interscience Publishers, New York, 1954, p. 253.
- [3] Henry, R. D., Clinical Chemistry, Principles and Practice, pp. 262-276, Hoeber Medical Division, Harper & Row, New York, N. Y. 10016 (1967).
- [4] Tietz, N. W., Fundementals of Clinical Chemistry, pp. 718-722, W. B. Saunders Co., Philadelphia, Pa. 19105 (1970).

This Standard Reference Material has been measured and certified at the laboratories of the National Bureau of Standards, Gaithersburg, Maryland. All inquiries should be addressed to:

Office of Standard Reference Materials Room B311, Chemistry Building National Bureau of Standards Washington, D. C. 20234

The date of issuance and certification of this Standard Reference Material was September 24, 1968.