



## **CERTIFIED REFERENCE MATERIAL CERTIFICATION REPORT**

This report details the preparation and certification of the following Certified Reference:

<b>PRODUCT:</b>	5 % Sucrose In Water
<b>PRODUCT NO:</b>	BS05
<b>LOT NO:</b>	BS0524G1
<b>DATE OF MANUFACTURE:</b>	10 July 2024
<b>EXPIRY DATE:</b>	21 November 2024
<b>SPECIFICATION:</b>	Mass fraction of 4.8 - 5.2 %
<b>CERTIFIED MASS FRACTION:</b>	4.99 ± 0.15 %

Equivalent °Brix value is 4.99

Equivalent refractive index @ 20°C from ICUMSA Methods Book 2009 Appendix 1, Equation (1), SPS-3(2000) is 1.340249 using sodium light at 589.0nm.

### **Intended Use:**

This Certified Reference Material is intended primarily as either a calibrant or analytical control solution for use in Refractive Index based methods of Brix value determination.

### **TRACEABILITY IN THE PRODUCTION OF THIS STANDARD:**

This product was manufactured and certified in accordance with the requirements of ISO 17034. It was prepared gravimetrically on a mass/mass basis. All production and filling steps were carried out in a cleanroom environment. Both solute and solvent were weighed on balances calibrated by Reagecon engineers on the day of batch manufacture using SI traceable mass standards. Reagecon holds ISO/IEC 17025 accreditation for calibration of non-automatic weighing machines (6739-02). The resulting Balance Certificates of Calibration were issued in accordance with the requirements of ISO/IEC 17025. The certified value is expressed as an SI derived mass fraction.

The ambient conditions (temperature, pressure and humidity) were monitored during the production of this Certified Reference Material and the appropriate buoyancy corrections have been included in calculating the assigned value.

The process used to manufacture this Certified Reference Material has been verified using NIST SRM 17f and independent analysis by a second National Metrology Laboratory.

As a further control the mean value determined from the Homogeneity samples for each batch is checked against the gravimetrically assigned value. If the values do not agree within the uncertainty of the test method (LAB-P-TPRIA 01) the batch is rejected.

The mass of sucrose used to prepare this Certified Reference Material was adjusted for the purity of the raw material. The assay of this high purity sucrose was assigned by subtracting determined sulphated ash (ICUMSA Method GS1-10 (1998)), moisture (ICUMSA Method GS2/1/3/9-15 (2007)) and reducing sugars (ICUMSA Method GS2/9-6 (2007)) contents from 100 %. The absence of any other significant impurities was verified by determination of the polarisation value of the sucrose according to ICUMSA Method SPS-1 (2009).

### **Details of the balance(s) used in the manufacture of this batch**

<b>Balance ID No.</b>	RRD077
<b>Balance Calibration Date:</b>	20 June 2024
<b>Calibration Certificate:</b>	B40004

**Calibration Authority For Balance(s):** Reagecon Diagnostics Ltd, ISO/IEC 17025 Accreditation No. 6739-02 (A2LA).

## **CERTIFICATION REPORT (continued)**

**LOT NO:** BS0524G1

### **UNCERTAINTY OF THE ASSIGNED VALUE:**

The reported uncertainty was calculated in compliance with ISO 17034 and EAL Publication EA4/02 and includes uncertainty contributions due to the purity assessment of the raw material, the gravimetric preparation of the solution, the homogeneity of the filled batch and the stability of the solution over time. It is calculated with a coverage factor of 2 ( $k=2$ ) to provide a confidence level of approximately 95 %.

### **Details of the unexpanded uncertainty components used to compute the uncertainty of assigned value of this batch.**

Uncertainty component due to raw material assay and gravimetric preparation:	0.0003 %
Uncertainty component due to (in)homogeneity effects:	0.0001 %
Uncertainty component due to changes during transport:	0.0001 %
Uncertainty component due to changes during storage (at recommended temperature):	0.0037 %

Stability studies carried out by Reagecon Diagnostics Ltd have shown that this certified reference material can be exposed to a temperature of 40°C for two full weeks without extra degradation (over and above normal storage degradation) occurring. Temperature tracking of random shipments to customers worldwide over a two year period have reported a maximum exposure exceeding 30°C, but less than 40°C for a period of less than 1 day only. For this reason no extra allowance is made for transport conditions in the computation of the assigned uncertainty.

### **ASSESSMENT OF HOMOGENEITY:**

The certified mass fraction and the homogeneity of the batch were verified by the analysis of ten samples of this lot taken at time of manufacture, with testing being performed in such a manner as to eliminate the impact of any drift during testing. The analysis was carried out using a high performance calibrated, temperature controlled refractometer according to Reagecon's ISO/IEC 17025 accredited method LAB-P-TPRIA 01. This product is homogeneous provided that the instructions for use are followed.

### **STABILITY OF THIS CERTIFIED REFERENCE MATERIAL:**

The stability of this reference material is assured until the expiry date, provided that the instructions for use are followed. This reference material will be monitored throughout its shelf life and any changes in value will be reported to all purchasers.

### **COMMUTABILITY:**

This Certified Reference Material is intended primarily as either a calibrant or analytical control solution for use in Refractive Index based methods of Brix value determination. Commutability to other measurement methods has not been assessed.

### **ACCREDITATION:**

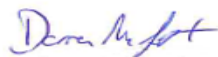
Reagecon Diagnostics Ltd is accredited by the American Association for Laboratory Accreditation, under scope 6739.01, for the gravimetric preparation of sucrose/ water solutions (ISO 17034).

Reagecon Diagnostics Ltd is accredited by the American Association for Laboratory Accreditation, under scope 6739.03 for test method LAB-P-TPRIA 01 for the determination of Brix values by Refractive Index measurement (ISO/IEC 17025).

Reagecon Diagnostics Ltd is accredited by the American Association for Laboratory Accreditation, under scope 6739.02, for the calibration of non-automatic weighing machines (ISO/IEC 17025).

### **INSTRUCTIONS FOR USE:**

- Prior to use, the contents of the dropper bottle should be brought to room temperature and mixed thoroughly by inversion to ensure a homogeneous mix.
- Remove cap and discharge 4-5 droplets of liquid to waste to clear the nozzle.
- Replace cap immediately after use.
- Product must be stored at +2°C to +8°C when not in use.
- DO NOT FREEZE.
- Refer to the product Safety Data Sheet for detailed safety information regarding this product.
- NOTICE AND WARNING TO USERS :- Stability of the product is guaranteed for the stated shelf life provided it is handled and stored in accordance with Good Laboratory Practice and the Instructions For Use are followed.

Approved Signatory:	Darren McGrath	Quality Director	
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**CERTIFICATE ISSUE DATE:** 07 August 2024

This certificate must not be reproduced except in full.

**CERTIFICATE ISSUE NUMBER:** 1