

## Certified Reference Material Reference material certificate

### Lactose Standard for IC

**TraceCERT®**  
Traceable Certified Reference Materials

**Product no.:** 72622  
**Lot no.:** BCKK3152  
**Description of CRM:** Lactose (pure material) in high-purity water (18.2 MΩ·cm, 0.22 μm filtered). The HDPE bottles are x-ray sterilized and the solution is additionally filtered through a 0.2 μm membrane and bottled under clean room conditions.  
**Expiry date:** APR 2025  
**Storage:** Store at 5°C ± 3°C  
**Density (certified) at 20°C:** 998.7 kg m<sup>-3</sup> ± 0.5 kg m<sup>-3</sup>

**Constituent** Certified values at 20°C and expanded uncertainties,  $U = k \cdot u$  ( $k = 2$ ) [1][2]

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Lactose (C <sub>12</sub> H <sub>22</sub> O <sub>11</sub> )	1001 mg kg <sup>-1</sup> ± 6 mg kg <sup>-1</sup> 1000 mg L <sup>-1</sup> ± 6 mg L <sup>-1</sup>

**Metrological traceability:** Certified values are traceable to the International System of units (SI) through a metrologically valid weighing process. Details see "Details on metrological traceability".<sup>[3]</sup>

**Measurement method:** The certified value is determined by high-precision weighing of thoroughly characterized starting materials and verified by measurement against NIST SRMs or similar CRMs in accordance with ISO/IEC 17025.<sup>[4]</sup>

**Intended use:** Calibration of ion chromatography or any other analytical technique.

**Instructions for handling and correct use:** The bottle's temperature must be 20°C. Shake well before every use. If storage of a partially used bottle is necessary (at the user's risk), the cap should be tightly sealed and the bottle should be stored at reduced temperature (e.g. refrigerator) to minimize transpiration rate.

**Health and safety information:** Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

**Packaging:** 50 mL HDPE bottle

**Accreditation:** Sigma-Aldrich Production GmbH is accredited by the Swiss Accreditation Service SAS as reference material producer under no. SRMS 0001 in accordance with international standard ISO 17034<sup>[5]</sup>

**Certificate issue date:** 08 JUN 2023



ISO 17034  
SRMS 0001

S. Matt

S. Matt – CRM Operations

Dr. P. Zell

Dr. P. Zell – Approving Officer



### Certification process details:

The certified concentrations and expanded uncertainties of the analyte are based on the results obtained from gravimetric production and from the analytical results determined using mass balance approach.

Gravimetric preparation using well defined and pure materials is a practical realization of concentration units, through conversion of mass to amount of substance<sup>[2]</sup>. All high-precision balances are periodically calibrated by a third party and certified according to DKD guidelines.

Production and certification of this CRM are in accordance with **ISO 17034**<sup>[5]</sup>. Storage stability, leaching and homogeneity tests are also considered for certification.

### Details on metrological traceability:

For pure materials ( $P > 99\%$ ) the most appropriate way of purity determination is to quantify the impurities ( $w_i$ ) and to subtract the sum from 100%.

$$P = 100\% - \sum_i w_{i, \text{found}}$$

Starting material	Starting material content with expanded uncertainty	Traceable to
<b>Lactose</b> P/N PHR1025 Lot LRAD1878	<b>99.7% +/- 0.5%</b>	SI unit kg by mass balance

The methods applied for the determination of impurities are High-performance liquid chromatography, GC-MS headspace and gravimetric analysis.

### Homogeneity assessment:

Due to the production process, a homogeneous solution derives. Nevertheless a small homogeneity contribution is included into the calculation of content uncertainty of this CRM.

### Stability assessment:

Two major contributors to the overall stability of this CRM were evaluated in deep. The mass loss due to evaporation is driven by the storage temperature and the geometry and the material of the bottle used. The bottles were tested for long term weight loss due to evaporation at different temperatures. The effect was taken into account in the uncertainty contribution of the storage stability. The microbiological stability was assessed with microbiological testing of the bottled solution. No biological contamination could be detected.

### Density Measurement:

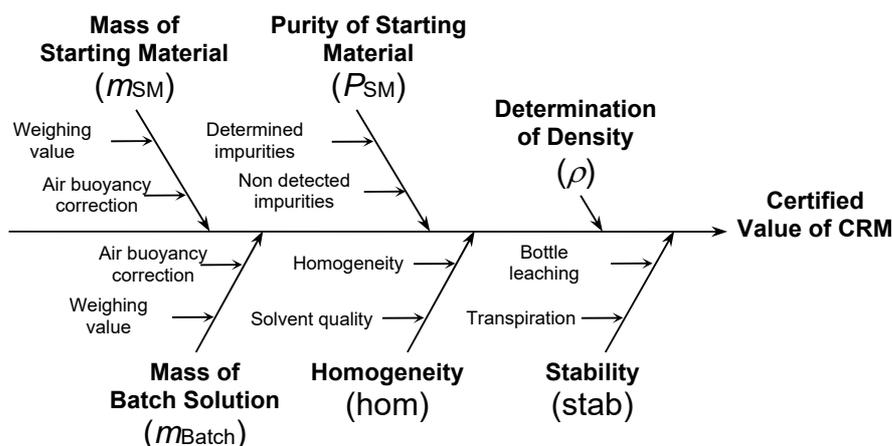
The density measurement is carried out in accordance with ISO/IEC 17025<sup>[4]</sup> and ISO 15212-1<sup>[6]</sup> using the digital density meter DMA 4500M from Anton Paar with an oscillating U-tube installed. The measurement uncertainty is calculated according to Eurachem/CITAC Guide and reported as combined expanded uncertainty at the 95% confidence level, using a coverage factor of  $k = 2$ .

## Uncertainty evaluation:

The uncertainty contributions are illustrated by the following cause-effect diagram [7]:

Typical relative contributions are:

$u(m_{SM})$	< 0.01 %
$u(m_{Batch})$	< 0.01 %
$u(P_{SM})$	< 0.25 %
$u_{hom}$	< 0.03 %
$u_{stab}$	< 0.14 %
$u(\rho)$	< 0.05 %



The combined standard uncertainty is calculated by combination of the standard uncertainties of the input estimates according to Eurachem/CITAC Guide "Quantifying Uncertainty in Analytical Measurement" and ISO 17034.[2][5]

Expanded uncertainty is then calculated to a confidence level of 95%, typically by multiplying with a confidence level factor of  $k=2$ .

## References:

- [1] ISO Guide 35:2017, "Reference materials - Guidance for characterization and assessment of homogeneity and stability"
- [2] Eurachem/CITAC Guide, 3<sup>rd</sup> Ed. (2012), "Quantifying uncertainty in analytical measurement"
- [3] Eurachem/CITAC Guide, 2<sup>nd</sup> Ed. (2019), "Metrological Traceability in chemical measurement"
- [4] The accredited testing laboratory STS 0490 performs the measurements and weighing steps for the certification of this CRM under ISO/IEC 17025:2017, "General requirements for the competence of testing and calibration laboratories"
- [5] ISO 17034:2016, "General requirements for the competence of reference material producers"
- [6] DIN EN ISO 15212-1:1998, Oscillation-type density meters - Part 1: Laboratory instruments
- [7] Reichmuth, A., Wunderli, S., Weber, M., Meyer, V. R. (2004), "The uncertainty of weighing data obtained with electronic analytical balances", *Microchimica Acta* 148: 133-141.

## Certificate of analysis revision history:

Certificate version	Certificate issue date	Reason for version
01	08 JUN 2023	Initial version

## Disclaimer:

The purchaser must determine the suitability of this product for its particular use. Sigma-Aldrich Production GmbH makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Sigma-Aldrich Production GmbH. We do not guarantee that the product can be used for a special application.

