Specification

Certipur® Certified Reference Material

Producer: **Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany.**

Accreditation:

DAkkS Deutsche Akkreditierungsstelle D-RM-15185-01-00

Merck KGaA, Darmstadt, Germany is accredited by the German accreditation authority DAkkS as registered reference material producer D-RM-15185-01-00 in accordance with **ISO Guide 34** and registered calibration laboratory D-K-15185-01-00 according **to DIN EN ISO/IEC 17025.**

Description of CRM: **Certified secondary standard reference buffer solution pH(S) 9.18$_0$ (25°C)**
certified reference material for pH measurement

Ord. No.: 1.07203.0105

Lot No.: example

Composition: di-sodium tetraborate decahydrate in water
Formulation in compliance with DIN 19266, IUPAC, NIST, European Pharmacopeia (Ph. Eur.) and United States Pharmacopeia (USP)
Molality: 0.01 mol/kg

Certified value and uncertainty: This certified secondary standard reference buffer solution is certified for a temperature range from 5°C-50°C. See example below:

T [°C]	certified pH ± U_{CRM}
5.0	9.380 – 9.400 ± 0.044
10.0	9.319 – 9.339 ± 0.044
15.0	9.265 – 9.285 ± 0.044
20.0	9.216 – 9.236 ± 0.044
25.0	9.171 – 9.191 ± 0.044
30.0	9.131 – 9.151 ± 0.044
37.0	9.084 – 9.104 ± 0.044
40.0	9.065 – 9.085 ± 0.044
45.0	9.035 – 9.055 ± 0.044
50.0	9.008 – 9.028 ± 0.044

pH value with expanded uncertainty U_{CRM}

Method of Analysis: The pH value is directly measured by differential potentiometry with the aid of two platinum hydrogen electrodes “quasi without transference” according to IUPAC[1] recommendations against solutions prepared from primary reference materials from characterised by PTB and NIST.

Minimum shelf life: 2 years

ISO GUIDE 34 · Accredited as CRM Producer and Calibration Laboratory · DIN EN ISO/IEC 17025 ·

(Laboratory manager)

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Traceability:

This certified secondary standard reference buffer solution is directly traceable to the primary certified reference material di-sodium tetraborate decahydrate (characterised by PTB) and NIST.
NIST xxx
PTB xxx
PTB: Physikalisch Technische Bundesanstalt, Braunschweig, Germany
NIST: National Institute of Standards and Technology, Gaithersburg, USA.

Preparation:

This reference material is prepared gravimetrically from di-sodium tetraborate decahydrate and high purity water. The formulation is compliant to DIN 19266, IUPAC[1], NIST[2], Ph. Eur. chapter 2.2.3 and USP chapter <791>.

Storage:

+15°C to +25°C tightly closed in the original container

Application and correct use:

This reference material is intended for use as a calibration standard for pH instruments or pH electrodes. The pH value strongly depends on the temperature. Therefore it is necessary to keep the temperature constant during the measurement. Details concerning the nature of any hazard and appropriate precautions are provided in the material safety data sheet.

Expanded uncertainty U_{CRM}:

The expanded uncertainty U_{CRM} is calculated as $U_{CRM} = k \cdot u_{CRM}$, where $k = 2$ is the coverage factor for a 95% coverage probability and u_{CRM} is the combined standard uncertainty in accordance to ISO Guide 34.

$$u_{CRM} = \sqrt{u^2_{Characterisation} + u^2_{Homogeneity} + u^2_{Stability}}$$

The combined standard uncertainty u_{CRM} is obtained from the standard uncertainties of the characterisation, the homogeneity and the stability.

$u_{Characterisation}$ is the uncertainty in accordance to DIN EN ISO/IEC 17025 which includes the contributions of the primary reference material and the measuring system.

$u_{Homogeneity}$ is the between-bottle variation in accordance to ISO Guide 34. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen sample units.

$u_{Stability}$ is the uncertainty obtained from short-term and long-term stability in accordance to ISO Guide 34. The stability studies are the basis for the quantification of the minimum shelf life of this reference material for the unopened bottle.

For more detailed information please read the certification report on www.merckmillipore.com

[1] R.P. Buck, S. Rondinini, A. K. Covington, F.G.K. Baucke, C. M. A. Brett, M. F. Camoes, M. J. T. Milton, T. Mussini, R. Naumann, K. W. Pratt, P. Spitzer, G. S. Wilson: **The Measurement of pH – Definition, Standards and Procedures (IUPAC Recommendations 2002)**, Pure Appl. Chem, Vol 74, No. 11, pp. 2169-2200, 2002

[2] Y. Ch. Wu, W. F. Koch, R. A. Durst: **Standardization of pH Measurements**, NBS Special Publication 260-53, 1988