Specification – Certified Reference Material

Aquastar® Sodium tartrate dihydrate

Accreditation:

Merck KGaA, Darmstadt, Germany is accredited by the German accreditation authority as registered reference material producer (D-RM-15185-01-00) in accordance with **ISO 17034**.

Producer:	Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Product no.:	1.06664.0100
Description of CRM:	Sodium tartrate dihydrate Certified Reference Material for Karl Fischer titration, 15.66%, Aquastar®
Expiry date:	2 years
Storage:	+15°C to +25°C tightly closed in the original container
Composition:	Sodium tartrate dihydrate

Analyte	Specification as mass fraction	Associated uncertainty, $U=k\cdot u$ ($k=2$) as mass fraction
Water	**15.61 – 15.71%**	**±0.05%**
	156.1 – 157.1 mg/g	**±0.5 mg/g**

Metrological traceability:	Directly traceable to SI Unit (kg).
Measurement method:	The water content is determined by loss on drying at 150°C.
Intended use:	This certified reference material is intended for use as a standard for standardisation of the volumetric Karl Fischer titrants. It can also be used to standardise the titrant according to European Pharmacopeia (Ph.Eur.) chapter 2.5.12 "Water Semi-Micro Determination" and according to United States Pharmacopeia <921> "Water Determination" as well as according to ISO 760.

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Certification process details:

This Aquastar® Karl Fischer standard is prepared gravimetrically from high purity salts.

Characterisation of Aquastar® Karl Fischer standard Sodium tartrate dihydrate is carried out by the accredited quality control (QC) laboratory at Merck KGaA, Darmstadt, Germany according to DIN EN ISO / IEC 17025 by measuring the water content by loss on drying.

Homogeneity and stability studies are performed with the material according to the requirements of ISO 17034 and ISO 33405.

Associated uncertainty:

The associated uncertainty U_{CRM} reported with the certified values is calculated as combined expanded uncertainty $U_{CRM}=k \cdot u_{CRM}$ in accordance with GUM and EA-4/02, with $k=2$ as the coverage factor for a 95% coverage probability.

The combined uncertainty u_{CRM} is derived from combination of the squared uncertainty contributions:

$$\boldsymbol{u}_{\mathrm{CRM}} = \sqrt{\boldsymbol{u}^2_{\mathrm{characterisation}} + \boldsymbol{u}^2_{\mathrm{homogeneity}} + \boldsymbol{u}^2_{\mathrm{stability}}}$$

$\boldsymbol{u}_{\mathbf{characterisation}}$:	is the uncertainty in accordance with DIN EN ISO/IEC 17025 which includes e. g. contributions of the primary reference material and the measuring system. $\boldsymbol{u}_{\mathbf{characterisation}}$ in the certified value is calculated in accordance to EA-4/02 and GUM. $\boldsymbol{U}_{\mathbf{characterisation}}$ is 0.01% (0.1 mg/g) (calculated as $U_{\mathrm{characterisation}} = k \cdot u_{\mathrm{characterisation}}$ with $k=2$)
$\boldsymbol{u}_{\mathbf{homogeneity}}$:	is the between-bottle variation in accordance with ISO 17034. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen sample units.
$\boldsymbol{u}_{\mathbf{stability}}$:	is the uncertainty obtained from short-term and long-term stability in accordance with ISO 17034. The stability studies are the basis for the quantification of the expiry date of this water standard for the unopened bottle.

Detailed information is provided by the certificates and the certification report on our website.