



Certificate of Analysis

Certified Reference Material

ETOH-1

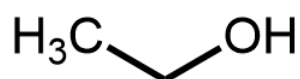
Certified Reference Material for High Purity Ethanol

ETOH-1 is a certified reference material (CRM) designed for ethanol measurements where accuracy is critical, such as the assessment of ethanol purity destined for use in hand sanitizers or for verification of ethanol solutions used in the evaluation of alcohol breath testing devices. It also contains acetaldehyde at a level just under the 10 ppm limit in ethanol for use in hand sanitizers in Canada [1], based on limits set by the British, European, and US pharmacopeia, and therefore would be suitable for method validation and quality control to support the analysis of acetaldehyde in ethanol. Certified values for the mass fraction and mass concentration of ethanol in ETOH-1 have been established, as listed in Table 1. Information values for the mass fraction and mass concentration of an acetaldehyde impurity in ETOH-1 are provided in Table 2.

Table 1: Certified values and expanded uncertainties ($k = 2$) for ETOH-1

Compound	Mass fraction g/g	Mass concentration g/mL (21 °C)
ethanol (a)	0.9968 ± 0.0052	0.7845 ± 0.0090

Refer to the sections below for additional explanations



ethanol

CAS registry number: [64-17-5](#)

InChIKey: [LFQSCWFLJHTTHZ-UHFFFA0YSA-N](#)

Molecular formula: C₂H₆O

Molar mass: 46.07 g/mol

Period of validity: until December 2030

Storage conditions: 4 °C or below

Table 2: Information values for ETOH-1

Compound	Mass fraction µg/g	Mass concentration µg/mL (21 °C)	Additional information
acetaldehyde (b)	8.32	6.55	C ₂ H ₄ O, CAS: 75-07-0

Intended use

Distributed in 1 mL units, this certified reference material is primarily intended for use in method development and in the calibration of instrumentation for the quantitative analysis of ethanol.

Preparation of material

The material was acquired from a commercial supplier and was used as received. The ethanol was dispensed in 1 mL aliquots in clean amber glass ampules. The ampules were immediately flame-sealed in a controlled environment at 40 % relative humidity.

Characterization of material

The explanatory list of letters next to each compound (Table 1 and 2) refers to the instrumental method used for measurements:

- a) Internal standard quantitative nuclear magnetic resonance spectroscopy (¹H-qNMR)
- b) Headspace gas chromatography tandem mass spectrometry (HS-GC-MS/MS) combined with standard addition calibration

The mass concentration values reported were calculated from the mass fraction values using a density of 0.787 ± 0.008 g/mL ($k = 2$, 95 % confidence interval) at 21 °C determined at the NRC on the actual CRM. However, note that the density of ethanol changes by 0.11 % per degree Celsius (in the interval of 10 to 30 °C; decreasing density with increasing temperature).

Metrological traceability

Results presented in this certificate are traceable to the International System of Units (SI) through gravimetrically prepared standards of NIST SRM 84L potassium hydrogen phthalate employed as an internal standard for ¹H-qNMR.

Homogeneity

The material is expected to have a high degree of homogeneity as it is a liquid of high purity. Nevertheless, the homogeneity was tested at the NRC using ¹H-qNMR. Results from a representative number of ampules across the fill series were evaluated using the DerSimonian-Laird (DSL) random effects model [2]. The between-unit variability was determined to be negligible for ethanol in ETOH-1, therefore, the material is deemed to be homogeneous.

Stability

The transportation stability of ethanol in ETOH-1 was assessed using ¹H-qNMR at four- and twelve-week time points after exposure to +50 °C. No significant degradation was observed during this period. The long-term stability of ethanol in ETOH-1 at +4 °C was assessed after five years using ¹H-qNMR and compared to the certified value. No significant difference in the measured mass fraction was observed over this period. Therefore, the uncertainty components for transportation and long-term stability were set to zero.

Uncertainty

The expanded uncertainty (U) for all values is equal to $U = ku_c$, where u_c is the combined standard uncertainty calculated according to the Joint Committee for Guides in Metrology (JCGM) [3] and

k is the coverage factor. A coverage factor of $k = 2$ was applied which corresponds to a level of confidence of approximately 95 %.

All reasonable sources of uncertainty related to the certified values in Table 1 were considered. Included in the combined uncertainty estimate are uncertainties in the batch characterization, uncertainties related to possible between-unit variation, and uncertainties related to stability.

Storage

The material shall be stored at 4 °C or below. The ampoule should be stored unopened.

Instructions for handling and use

Prior to opening, each ampoule should be allowed to equilibrate to room temperature and the contents thoroughly mixed. The ampoule should be opened at the pre-scored mark immediately prior to use. The certified value is only guaranteed if the ampoule is sampled immediately after opening in order to limit solvent evaporation. It is important to note that the volume of the solution is not certified; only the concentration is certified. Therefore, the entire contents of the vial should not be diluted to volume.

Repeated sub-sampling and storage of the CRM solution after initial opening may impact certified values. Users shall take responsibility for demonstrating that their sub-sampling and storage procedures do not impact certified values.

Health and safety information

Only qualified personnel should handle the material and appropriate disposal methods should be used. A Safety Data Sheet (SDS) is available at doi.org/10.4224/crm.2020.etoh-1. For laboratory use only; not for human consumption, therapeutic, drug, household, or any other uses.

Period of validity

The certified values are valid until December 2030, provided the storage and instructions for handling and use specified in this certificate are followed.

Quality Management System

The NRC is Canada's national metrology institute (NMI) and is a signatory of the International Committee for Weights and Measures Mutual Recognition Arrangement (CIPM MRA). The CIPM MRA was developed in a response to a growing need for an open, transparent, and comprehensive scheme to give users reliable quantitative information on the comparability of national metrology services and to provide the technical basis for wider agreements negotiated for international trade, commerce, and regulatory affairs. Our Quality Management System for measurement services and certified reference materials conforms to the requirements of ISO/IEC 17025 and ISO 17034.

Description of terms

Certified values are those for which the NRC has the highest confidence and that all known and suspected sources of bias have been considered by the NRC and are reflected in the stated expanded uncertainties.

Information values are those that may be of interest to users, but for which the NRC has not established sufficient information to provide an estimate of uncertainty, or that reflect a lack of agreement between different methods of analysis.

Supplemental information

Bibliographic information and any additional technical supplemental information is available at doi.org/10.4224/crm.2020.etoh-1.

References

1. Government of Canada. (2020, May 9). Interim guidance for producing ethanol for use in alcohol-based hand sanitizers. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/interim-guide-ethanol-hand-sanitizers.html>. Accessed: 04 December 2020.
2. JCGM 100:2008. Evaluation of measurement data – Guide to the expression of uncertainty in measurement. Joint Committee for Guides in Metrology (JCGM); 2008. <https://doi.org/10.59161/JCGM100-2008E>
3. DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials (1986), 7: 177-188. [https://doi.org/10.1016/0197-2456\(86\)90046-2](https://doi.org/10.1016/0197-2456(86)90046-2)

Authorship

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January 2025 (stability section updated, date of expiry extended, editorial updates)

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Approved by: _____

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This certificate is only valid if the corresponding material was obtained directly from the NRC or an authorized reseller. Users should ensure that the certificate they have is current. For updates, please refer to doi.org/10.4224/crm.2020.etoH-1.

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The logo for Canada, featuring the word "Canada" in a serif font with a small Canadian flag to the right of the letter "a".