Supelco®

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# Certificate of Analysis

## Certified Reference Standard - NIST Traceable

## Ethanol-200

*Ethyl alcohol*

| | |
|---|---|
| **Catalog Number:** | E-032 |
| **Solution Lot:** | FN03132302 |
| **Expiration:** | March 2028 |
| **Diluent:** | Water |
| **Volume per Ampule:** | 1.2 mL |
| **Storage:** | Refrigerate (Do Not Freeze) |
| **Country of Origin:** | Canada |
| **Intended Use:** | For R&D/ analytical purposes only. Not suitable for human or animal consumption. |

- Expiration Date has been established through real time stability studies and applies to the ampoule stored unopened at the recommended storage condition.
- Ampoules are overfilled to ensure a minimum 1.2 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration. The standard should be used immediately after opening to avoid concentration changes due to evaporation.
- For quantitative applications, the minimum sample size for intended use is 100 µL.

| Component | Solution Purity | Certified Concentration |
|---|---|---|
| Ethanol | > 99.9% | 200 ± 1 mg/dL |

- Uncertainty of the concentration, expressed in terms of volume, is an expanded uncertainty in accordance with ISO 17025 and ISO 17034 at the 95% confidence interval using a coverage factor of k=2 and has been calculated by statistical analysis of our production methods applicable to ethanol reference standards and incorporates uncertainty of the purity factor, material density and mass measurement. The dispensing process is sufficiently controlled as to not be a significant contributor to uncertainty calculations and is, therefore, excluded. Solution stability is established through real time stability studies and is, therefore, excluded.
- When expressed in percentage terms, the relative standard uncertainty of the concentration is 0.249% and the relative expanded uncertainty is 0.50% at the 95% confidence interval (k=2).
- The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.
- Purity factor has been established through independent certification of the neat analyte to ISO 17025 standards – See page 3.
- Solution purity is verified post ampouling and demonstrates no contamination or degradation has occurred.

Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date. Warranty applies to ampoules stored unopened and stored under the recommended storage conditions. Warranty and expiry do not extend to solutions into which this product has been incorporated. Establishment of shelf life of all such products is the responsibility of the user.

ANAB ANSI National Accreditation Board ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

***April 14, 2023***
Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock,
TX 78665, USA, Tel: 800-848-7837 / 512-238-9974; www.cerilliant.com
Sigma-Aldrich Production GmbH is a subsidiary of Merck KGaA, Darmstadt, Germany.

### *Traceability to SI through NIST:*

- This standard has been prepared and certified under the ISO 17034 and ISO/IEC 17025 standards and meets the requirements of a Certified Reference Material as defined by ISO.
- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified balances calibrated with NIST traceable weights.
- Concentration of this standard has been analytically verified against a NIST SRM and a Control using a validated method.

## Solution Standard Concentration and Batch Homogeneity

| Standard Solution | Lot Number | Comparison to NIST Lot SRM 2895 mg/dL | Homogeneity % RSD |
|---|---|---|---|
| New Lot | FN03132302 | 199 | 1.3 |
| Previous Lot | FN02052101 | 199 | 0.9 |
| Acceptance Criteria | | **± 2%** | **≤ 2** |

- Concentration is calculated as the average of multiple analyses conducted using a validated Headspace GC/FID method. The validated GC/HS method has been demonstrated to adequately detect and quantitate ethanol concentrations ranging from 5 to 600 mg/dL. Relative standard uncertainty of the analysis is 1.675% and includes both uncertainty of the analytical method and uncertainty of the NIST SRM concentration.
- The Control is independently prepared from a different lot of neat ethanol to ensure no bias in the analysis and independently qualified against a NIST SRM.
- Homogeneity is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The %RSD of samples pulled from across the lot using a stratified random sampling plan demonstrates ampoule to ampoule consistency or homogeneity of the New Lot.
- The %RSD of the Previous Lot represents system suitability on the date of analysis. Triplicate injections of the Previous Lot are bracketed at the beginning and end of the sequence. %RSD criteria ensures proper system performance throughout the sequence.
- All instruments used for certification of the neat materials and verification of the solution concentration and homogeneity are fully qualified through an Installation Qualification and an Operational Qualification which is repeated annually. System suitability is performed daily with rigorous acceptance criteria to ensure the system continues to perform within the validated parameters.

### *Analyte Certification - Mass Balance Purity Factor*

*The purity factor (PF) mass balance measurement equation is used to calculate the amount of ethanol required to achieve an accurate concentration of the solution standard, accounting for both purity and residual water content.*

| ***Material Characterization Summary*** | | |
|---|---|---|
| **Analytical Test** | **Method** | **Results** |
| Chromatographic Purity by GC/FID Analysis | 20384346 | > 99.9% |
| Residual Water Analysis by Karl Fischer Coulometry | 20398075 [1] | 0.09% |
| Mass Balance Purity Factor | | 99.90% |

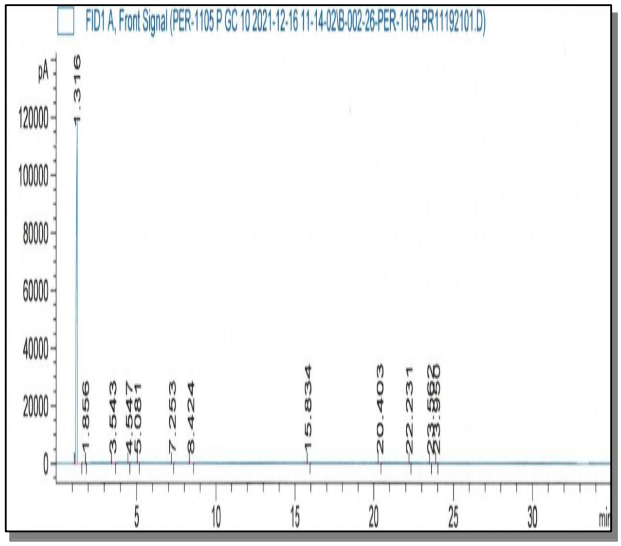
[1] Validated analytical method

- The chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.

### Spectral and Physical Data

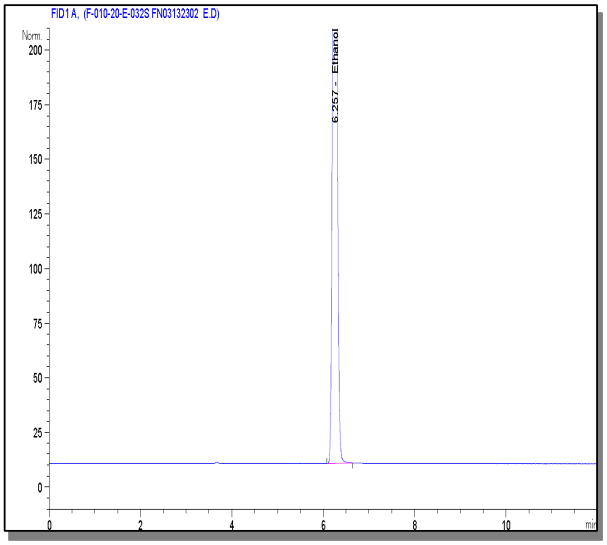
**Neat Material**

**Analysis Method:** GC/FID
**Column:** DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
**Temp Program:** 35°C hold 5 min to 100°C at 40°C/min
100°C to 280°C at 20°C/min hold 8 min
**Injector Temp:** Cool-on-Column
**Detector Temp:** 325°C




**Standard Solution**

**Analysis Method:** GC/FID Headspace
**Column:** DB-ALC1 30 m x 0.53 mm ID, 3.0 µm film thickness
**Temp Program:** 40°C hold 12 min
**Injector Temp:** 200°C
**Detector Temp:** 250°C



## *COA Revision History*

| Revision No. | Date | Reason for Revision |
|---|---|---|
| 00 | April 14, 2023 | Initial version. |
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