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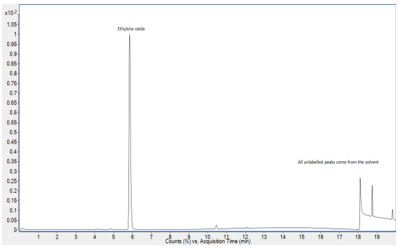
Certificate of Analysis - Certified Reference Material

Ethylene Oxide in DMA

Product no.: CAN1002-1.2ML
Lot no.: LRAD4357
Expiry Date: March 2026
Manufacturing Date: March 2023
Storage: ROOM TEMPERATURE
Solvent/Matrix: DIMETHYLACETAMIDE
Certificate version: LRAD4357.01 (*Note: Certificates may be updated due to the availability of new data. Check our website at: www.sigma-aldrich.com for the most current version.)*

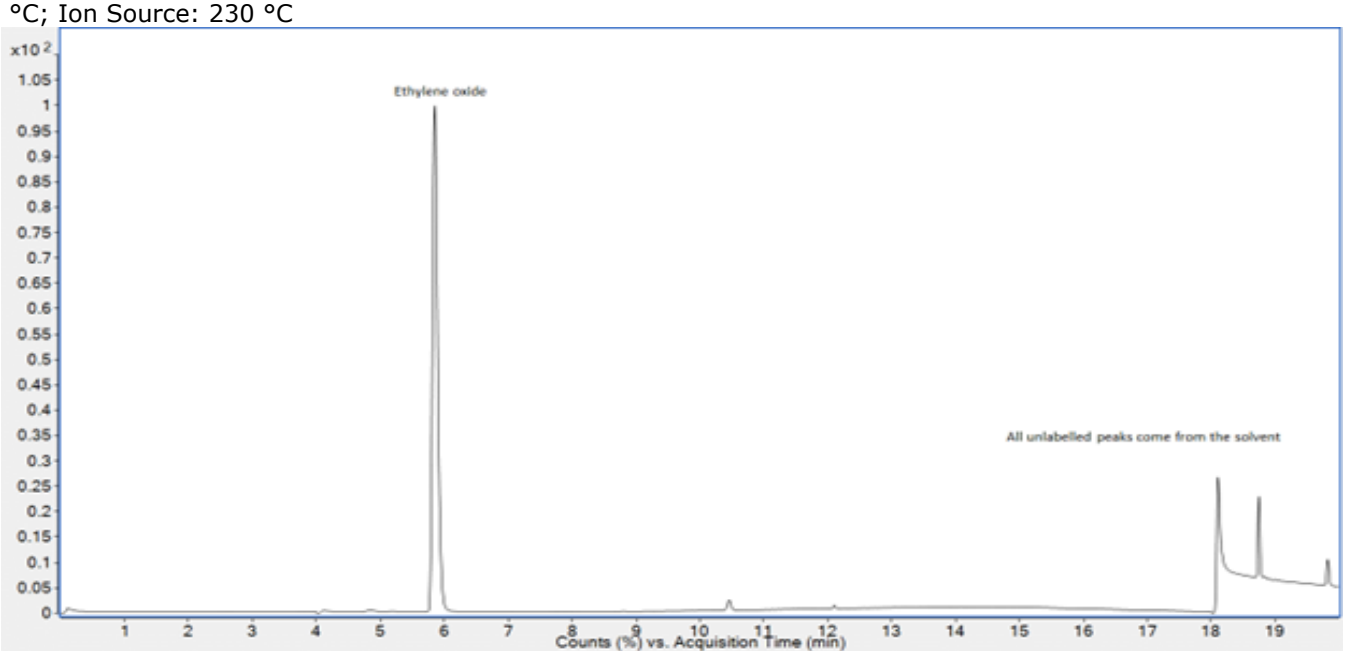


Certified Values:

Analyte	*Certified Value*	*Units*	*Raw Material Purity,%*	*Raw Material Lot*
ETHYLENE OXIDE CAS# 75-21-8	100.1 ± 6.4	µg/mL	99.5	MKCP9932

ASSAY Method

METHOD: GC (IN-HOUSE #1719)
Column: RTX-502.2, 60 m × 0.25 mm I.D., 1.4 µm film thickness
Carrier Gas: Helium Flow Rate: 1.5 mL/min
Inlet Temperature: 180 °C Injection Volume: 1.2 µL
Injection Mode: Split Ratio: 5:1
Temperature Program: 30 °C (Hold 8 min) @ 25 °C/min to 200 °C (Hold 5.2 min)
Detector: MSD; SIM Mode, Solvent delay: 0 min Temperature: Transfer Line: 200 °C; Quadrupole: 150 °C; Ion Source: 230 °C



Elution details:

EO	TIME	ANALYTE
1	5.85	Ethylene Oxide

Sigma-Aldrich RTC, 2931 Soldier Springs Rd. Laramie, WY 82070, USA;
Tel. 1 307-742-5452; Fax 1 855-831-9211; www.sigmaaldrich.com
Sigma-Aldrich RTC is a subsidiary of Merck KGaA, Darmstadt, Germany.

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. The balance used to weigh raw materials is accurate to +/-0.0001 g and calibrated regularly using mass standards traceable to NIST. All dilutions were performed gravimetrically. Additionally, individual analytes are traceable to NIST SRMs where available and specified above.

Measurement method: Where applicable, the assigned value is based on a purity determination by mass balance and gravimetrically prepared value.

Intended use: Intended for R&D and Analytical Use only. Not for drug, household or other uses.

Minimum sample size: 1.2 µL

Packaging: 1.2 mL in amber ampule

Instructions for handling and correct use: Use on the as is basis. The internal pressure of the container may be slightly different from the atmospheric pressure at the user`s location. Open slowly and carefully to avoid dispersion of the material.

Health and safety information: All chemical reference materials should be considered potentially hazardous and should be used only by qualified laboratory personnel. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Accreditation: Sigma-Aldrich RTC is accredited by the US accreditation authority ANAB as a registered reference material producer AR-1470 in accordance with ISO 17034.

Certificate issue date: 05 April 2023

Andy Ommen - QC Manager

Scott Stetler - QA Manager

Details on metrological traceability: 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 to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances. Further traceability to a corresponding Primary Standard may be achieved through a direct comparison assay. Where a Primary Standard is available, the assay value will be included in the specified section of the COA.

Associated uncertainty: Ucrm - Uncertainty values in this document are expressed as Expanded Uncertainty (Ucrm) corresponding to the 95% confidence interval. Ucrm is derived from the combined standard uncertainty multiplied by the coverage factor k, which is obtained from a *t*-distribution and degrees of freedom. The components of combined standard uncertainty include the uncertainties due to characterization, homogeneity, long term stability, and short term stability (transport). The components due to stability are generally considered to be negligible unless otherwise indicated by stability studies. The mathematical representation of the Ucrm calculation is as follows:

$$u_{CRM} = \sqrt{u_{char}^2 + u_{\text{hom}\ ogeneity}^2 + u_{stability}^2}$$

Homogeneity assessment: Homogeneity was assessed in accordance with ISO Guide 35. Completed units were sampled using a random stratified sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA. Heterogeneity was not detected under the conditions of the ANOVA.

Stability assessment: Significance of the stability assessment will be demonstrated if the analytical result of the study and the range of values represented by the Expanded Uncertainty do not overlap the result of the original assay and the range of its values represented by the Expanded Uncertainty. The method employed will usually be the same method used to characterize the assay value in the initial evaluation.

Certificate of analysis revision history:

Certificate version	Date	Reason for version
LRAD4357.01	05 April 2023	Original Release Date

Disclaimer: The purchaser is required to determine the suitability of this product for any particular application. Sigma-Aldrich RTC makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Sigma-Aldrich RTC. We do not guarantee that the product can be used for any particular application.