

CARBON DIOXIDE - carbon dioxide gas
Messer Merchant Production LLC

Carbon Dioxide Refrigerated Liquid USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

BULK CARBON DIOXIDE USP CERTIFICATE OF ANALYSIS

This is to certify that the carbon dioxide produced at _____ on _____ meets the United States Pharmacopeia (USP) specifications, the requirements of Federal Specifications BB-C-101 Grade A and QVL E of CGA G6.2. This product was manufactured at a facility registered with the Federal Food and Drug Administration and is approved for prescription drug use. This product is not guaranteed to meet any other specification or intended for pesticide use.

Furthermore, batch number _____ and lot number _____, which was loaded on _____ and filled at _____, comprises this shipment and was analyzed as shown below.

Analytical results are generated using USP monograph or validated equivalent methods.

| Requirement | Test Method | Limit of Detection | Specification Limit | Analysis Results |
|---|--------------------|---------------------------|----------------------------|-------------------------|
| Carbon Dioxide Assay (CO ₂) | Zahm Nagel | 99.00% | ≥ 99.0% | |
| Nitrogen Oxides (NO _x) | Detector Tube | 0.5 ppm | 2.5 ppm each | |
| Ammonia (NH ₃) | Detector Tube | 0.25 ppm | 25 ppm | |
| Total Sulfur | Analyzer | 10 ppb | 1000 ppb | |
| Carbon Monoxide (CO) | Detector Tube | 0.5 ppm | 10 ppm | |
| Moisture (H ₂ O) | Analyzer | 0.5 ppm | 200 ppm or -33°F Dew Point | |

Bulk Carbon Dioxide USP Certificate of Analysis

This is to certify that the carbon dioxide produced at _____ on _____, meets the United States Pharmacopoeia (USP) specifications, the requirements of Federal Specifications BB-C-101 Grade A and QVL E of CGA G6.2. This product was manufactured at a facility registered with the Federal Food and Drug Administration and is approved for prescription drug use. This product is not guaranteed to meet any other specification or intended for pesticide use.

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|--|--------------------------|---------------------------|--|-------------------------|
| Carbon Dioxide <u>Assay</u> (CO ₂) | Zahn Nagel / Analyzer | 99.99% | ≥99.0% | |
| Nitrogen <u>Oxides</u> (NO _x) | Detector Tube | 0.5 ppm | ≤2.5 ppm each | |
| <u>Ammonia</u> (NH ₃) | Detector Tube | 0.25 ppm | ≤25 ppm | |
| Total Sulfur | Analyzer | 10 ppb | ≤1000 ppb | |
| Carbon <u>Monoxide</u> (CO) | Detector Tube / Analyzer | 0.5 ppm | ≤10 ppm | |
| <u>Moisture</u> (H ₂ O) | Analyzer | 0.5 ppm | ≤200 ppm (150 mg/m ³ or -33° F Dew Point) | |

- Note:
- 1) Positive Carbon Dioxide Identification is achieved when the Assay results demonstrate meeting the specification.
 - 2) The limit of detection (LOD) for each test method is the threshold value for results to be reported with certainty in the accuracy of results. A test result outside the detection limit for the test method will be reported as ND.
 - 3) ND = None Detected
 - 4) ppm = parts per million by volume, ppb=parts per billion by volume, 1ppm=1,000 ppb
 - 5) H₂S, SO₂, and other sulfur species are included in the Total Sulfur amount

Product analyzed using Messer Premier Guard Analysis suite

Analyst: _____ Date: _____

Reviewed and released by: _____ Date: _____

CARBON DIOXIDE

carbon dioxide gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:45149-014 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| Carbon Dioxide (UNII: 142M471B3J) (Carbon Dioxide - UNII:142M471B3J) | Carbon Dioxide | 990 mL in 1 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:45149-014-01 | 18770 L in 1 TANK; Type 0: Not a Combination Product | 01/01/1965 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA205815 | 01/01/1965 | |

Labeler - Messer Merchant Production LLC (809567303)

Registrant - Messer Merchant Production LLC (831800201)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|---|
| Messer Merchant Production LLC | | 831800201 | manufacture(45149-014) , api manufacture(45149-014) |

Revised: 10/2024

Messer Merchant Production LLC