

CARBON DIOXIDE REFRIGERATED - carbon dioxide gas
Messer LLC

Carbon Dioxide

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.

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

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<i>Requirement</i>	<i>Test Method</i>	<i>Limit of Detection</i>	<i>Specification Limit</i>	<i>Analysis Results</i>
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 REFRIGERATED

carbon dioxide gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52438-014
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:52438-014-20	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	NDA205764	01/01/1965	

Labeler - Messer LLC (001368141)

Registrant - Messer LLC (001368141)

Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		833150639	manufacture(52438-014) , api manufacture(52438-014)

Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		020153345	manufacture(52438-014) , api manufacture(52438-014)

Establishment

Name	Address	ID/FEI	Business Operations
Messer LLC		004830011	manufacture(52438-014) , api manufacture(52438-014)