

NITROGEN- nitrogen gas
Indiana Oxygen Company, Inc.

Nitrogen

NITROGEN COMPRESSED LABEL

NITROGEN, COMPRESSED NF UN1066

NON-FLAMMABLE GAS 2 35149 (01/15)

Rx only. WARNING: Administration of Nitrogen may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of Nitrogen and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications and side effects and the precautions to be taken. **WARNING:** CONTAINS GAS UNDER PRESSURE; MAY EXPLODE, IF HEATED, MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION. Do not handle until all safety precautions have been read and understood. Use and store only outdoors or in a well-ventilated place. Use a back flow preventive device in the piping. Use only with equipment rated for cylinder pressure. Close valve after each use and when empty. Protect from sunlight when ambient temperature exceeds 52°C (125°F). Read and follow the Safety Data Sheet (SDS) before use. **FIRST AID; IF INHALED;** Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention. CAS: 7727-37-9 **DO NOT REMOVE THIS PRODUCT LABEL**

INDIANA OXYGEN COMPANY

6099 WEST CORPORATE WAY • INDIANAPOLIS, IN 46278

317-290-0003





NITROGEN REFRIGERATED LIQUID LABEL

REFRIGERATED LIQUID

NITROGEN, REFRIGERATED LIQUID NF UN1977

NON-FLAMMABLE GAS 2 (R-K14) 115149

↑ ALWAYS KEEP CONTAINER IN UPRIGHT POSITION. ↑

DO NOT CHANGE OR FORCE FIT CONNECTIONS.

RX ONLY

CONTENTS: _____ LTRS: ___ CU FT: ___

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WARNING: CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY. MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION.

Do not handle until all safety precautions have been read and understood.

Use and store only outdoors or in a well-ventilated place. Wear cold insulating gloves, face shield, and eye protection. Use a back-flow preventive device in the piping. DO NOT change or force fit connections.

Close valve after each use and when empty.

Always keep container in upright position.

Read and follow the Safety Data Sheet (SDS) before use.

FIRST AID: **IF INHALED:** Remove person to fresh air and keep comfortable for breathing.

IF ON SKING: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.

CAS: 7727-37-9

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6099 West Corporate Way

Indianapolis, IN 46278

317-290-0003

REFRIGERATED LIQUID

**NITROGEN,
REFRIGERATED
LIQUID
NF**

UN1977



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REFRIGERATED LIQUID

**NITROGEN,
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UN1977

2

(R-K14)

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NITROGEN CERTIFICATE OF ANALYSIS

Certificate of Analysis - Nitrogen NF Customer _____ Vendor / Supplier _____ This letter is to provide you with the certification you requested for Nitrogen NF, Lot number _____. supplied to you in cylinders / vessels by our location. These cylinders were filled in accordance with the standard operating procedures utilized for the manufacture of Medical Gases. By following these procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Regulations. CAUTION: Vendor supplies this certification to customer to assist customer in ensuring compliance with 21 CFR 211.84. This certification does not eliminate customer's obligation to comply with other portions of 21 CFR 210 and 211 including but not limited to 21 CFR 211.165 (finished product testing) for cylinders and vessels filled from these supply cylinders. These cylinders are not certified for instrument calibration purposes.

TEST/REQUIREMENT	NF SPECIFICATION	LOT ANALYSIS
IDENTIFICATION	PASS	
ODOR	NO APPRECIABLE ODOR	
OXYGEN	LESS THAN 1.0%	
CARBON MONOXIDE	LESS THAN 10 PPM	
ASSAY	GREATER THAN 99.0%	

THE METHODOLOGY BEING USED TO PERFORM THE NF TEST FOR ASSAY IS INDICATED BELOW:

_____ PARAMAGNETIC ANALYZER MODEL NUMBER

_____ ELECTROCHEMICAL ANALYZER MODEL NUMBER

_____ GAS CHROMATOGRAPHY OFFICIAL USP / NF METHOD

SUPPLIER SIGNATURE _____ DATE _____

J 700 a1 (01/03) BR COMPLIANCE ASSOCIATES LLC

LINDE LLC - Springville, Indiana

7996 N. State Rd 39, LaPorte, IN 46350

Certificate of Analysis - Stall 5

Product : NITROGEN NF

Date : 08/19/2016
Lot # 6498-081816-23
Tare Weight: 30740 lbs.
Gross Weight: 79680 lbs.
Net Weight: 48940 lbs.
Net Volume: 675.5 kscf

Batch # AIT-81-1-081816
Logon Time 08-19-16 02:23:21
Analysis Finish 08-19-16 03:00:13
Logoff Time 08-19-16 03:00:41

Final Analysis Results

Analyzer #	Test/Units	LIN1 Specs	Analysis Results	DL
Organoleptic	Odor	None	None	
AIT-81-1	ppm O2	<= 5.00	1.15	0.1
AIT-81-5	ppm CO	<= 10.00	0.22	0.06
N/A	ppm CO2	N/A	NT	
AIT-81-3	ppm H2O	N/A	NT	0.1
N/A	ppm THC	N/A	NT	
N/A	ppm H2	N/A	NT	
Assay Results (by difference)	Nitrogen min %	>= 99.0 (Linde Spec >= 99.999)	99.999780	

NT = Not Tested

ppm O2 Method Used : Electrochemical Manufacturer / Model # : Teledyne 316RA/3000T
ppm CO Method Used : Infrared Manufacturer / Model # : Siemens Ultramat

These analyzers have been validated by LINDE as acceptable alternatives to the official NF for Nitrogen Assay. Validation study documentation is maintained by LINDE at the production location and at 575 Mountain Avenue, Murray Hill, NJ 07974.

This document contains an electronic signature

Analyst	Date :
Electronically Analyzed by a Linde Medical Validated Automated Trailer Fill System	08/19/2016
Quality Reviewer	Date :
Chester Lesser	08/19/2016

Should the material not be delivered to a NF customer, the material is "Not Approved for Human Drug Use"

LIN1

LINDE LLC - Springville, Indiana

7996 N. State Rd 39, LaPorte, IN 46350

Certificate of Analysis - Stall 5

Product : NITROGEN NF

Date :	08/19/2016	Batch #	AIT-81-1-081816
Lot #	6498-081816-23	Logon Time	08-19-16 02:23:21
Tare Weight:	30740 lbs.	Analysis Finish	08-19-16 03:00:13
Gross Weight:	79680 lbs.	Logoff Time	08-19-16 03:00:41
Net Weight:	48940 lbs.		
Net Volume:	675.5 kscf		

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AIT-81-5	ppm CO	<= 10.00	0.22	0.06
N/A	ppm CO2	N/A	NT	
AIT-81-3	ppm H2O	N/A	NT	0.1
N/A	ppm THC	N/A	NT	
N/A	ppm H2	N/A	NT	
Assay Results (by difference)	Nitrogen min %	>= 99.0 (Linde Spec >= 99.999)	99.999780	

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LIN1

NITROGEN

nitrogen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48546-0003
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75)	NITROGEN	99 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48546-0003-1	6400 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
2	NDC:48546-0003-2	4220 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/1975	
3	NDC:48546-0003-3	1140 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
4	NDC:48546-0003-4	2280 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
5	NDC:48546-0003-5	3190 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
6	NDC:48546-0003-6	4890 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
7	NDC:48546-0003-7	6340 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
8	NDC:48546-0003-8	8420 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1975	
9	NDC:48546-0003-9	119935 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/1975	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205766	01/01/1975	

NITROGEN

nitrogen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48546-0005
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75)	NITROGEN	99.1 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48546-0005-1	136321 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/1975	
2	NDC:48546-0005-2	152339 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/1975	
3	NDC:48546-0005-3	152339 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/1975	
4	NDC:48546-	253908 L in 1 DEWAR; Type 0: Not a Combination	01/01/1975	

0005-4

Product

01/01/1975

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205766	01/01/1975	

Labeler - Indiana Oxygen Company, Inc. (006036776)**Registrant** - Indiana Oxygen Company, Inc. (006036776)**Establishment**

Name	Address	ID/FEI	Business Operations
Indiana Oxygen Company, Inc.		006036776	manufacture(48546-0003, 48546-0005)

Revised: 10/2022

Indiana Oxygen Company, Inc.