

NITROGEN NF- nitrogen gas
Norco, Inc

NITROGEN NF COA

N2 NF CoA

Truck# _____ Trailer # _____



Certificate of Analysis – Nitrogen NF

This letter is to provide you with the Certification for Nitrogen NF, Batch/Lot# _____ supplied to you in a trailer lot drop off from Norco, Inc.

For NF customers, by following Norco Medical Gas procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Practices (cGMP) Regulations and FDA Medical Gas Guidelines. When the NF test results below are completed and, **WHEN DELIVERED TO A PROPERLY FDA REGISTERED NF CUSTOMER**, they are intended to provide a Certificate of Analysis in keeping with current FDA guidance.

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

Test	NF Specification	Lot Analysis
Assay	> 99.0%	
Identification	Pass	
Odor	No appreciable odor	
Oxygen	≤ 1.0 %	
Carbon Monoxide	≤ 10 ppm	

The methodology used to perform the NF Test for Assay is indicated below:

Teledyne Trace Oxygen Analyzer Model # 3000TA
Siemens Carbon Monoxide Analyzer Model # Ultramat 6

These analyzers have been validated by Norco, Inc. as an acceptable alternative to the official NF Gas Chromatography method for Nitrogen Assay. Norco, Inc. maintains validation study documentation in the Quality Manager's office. All other tests (if applicable) performed by USP compendial methods.

Analysis By: _____ Date: _____

Reviewed & Released By: _____ Date: _____

**REFRIGERATED LIQUID
NITROGEN, REFRIGERATED
LIQUID NF
NON-FLAMMABLE GAS 2
UN1977**

41977 (12/14)

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 REFRIGERATED GAS: MAY CAUSE CRYOGENIC BURNS OR INJURY MAYDISPLACE 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 and keep comfortable for breathing.

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

CAS: 7727-37-9

DO NOT REMOVE THIS PRODUCT LABEL

NORCO1125 W. Amity ● Boise, Idaho 83705
(208) 336-1643

USPUN1977

REFRIGERATED LIQUID

**NITROGEN,
REFRIGERATED
LIQUID NF**



UN1977

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

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

CAS: 7727-37-9

DO NOT REMOVE THIS PRODUCT LABEL

Noreco

1125 West Amity • Boise, Idaho 83705
(208) 336-1643

USPUN1977

RES

NITROGEN NF HP LABEL

NITROGEN,

COMPRESSED NF

UN1066 NON-FLAMMABLE GAS 2

(R-K14)

CONTENTS: LTRS: _____ CU. FT. _____

WARNING: 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

precautions
ventilated
equipment rated
from
the Safety

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 Data Sheet (SDS) before use.

FIRST AID: IF INHALED: Remove person and keep comfortable for breathing. Get Medical/advice/attention.

CAS: 7727-37-9

DO NOT REMOVE THIS PRODUCT LABEL

NORCO 1125 W. Amity Rd.

Boise, Idaho 83705

(208) 336-1643

NITROGEN, COMPRESSED NF



UN1066

CONTENTS:

LTRS: CU.FT.

WARNING: 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.

Norco

1125 W. Amity Road
Boise, ID 83705
208-336-1643

NITROGEN NF

nitrogen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42602-005
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGEN (UNII: N762921K75) (NITROGEN - UNII:N762921K75)	NITROGEN	999 L in 1000 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42602-005-07	104359 L in 1 DEWAR; Type 0: Not a Combination Product	02/27/2003	
2	NDC:42602-005-08	116083 L in 1 DEWAR; Type 0: Not a Combination Product	02/27/2003	
3	NDC:42602-005-09	123900 L in 1 DEWAR; Type 0: Not a Combination Product	02/27/2003	
4	NDC:42602-005-10	156751 L in 1 DEWAR; Type 0: Not a Combination Product	02/27/2003	
5	NDC:42602-005-01	623 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	
6	NDC:42602-005-02	6457 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	
7	NDC:42602-005-03	382 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	
8	NDC:42602-005-04	3228 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	
9	NDC:42602-005-05	4021 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	
10	NDC:42602-005-06	6809 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	
11	NDC:42602-005-11	1190 L in 1 CYLINDER; Type 0: Not a Combination Product	02/27/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205805	02/27/2003	

Labeler - Norco, Inc (043694645)

Registrant - Norco, Inc (043694645)**Establishment**

Name	Address	ID/FEI	Business Operations
Norco, Inc		961763211	manufacture(42602-005)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc		363348041	manufacture(42602-005)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc		071401038	transfill(42602-005)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc		962460528	manufacture(42602-005)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		097817373	transfill(42602-005)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		182023523	transfill(42602-005)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		039050695	transfill(42602-005)