

**NITROGEN NF- nitrogen gas**  
**Norco, Inc**

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**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 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 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**

**NORCO** 1125 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

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**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 the Safety 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.

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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**

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

**Active Ingredient/Active Moiety**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

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

**Labeler** - Norco, Inc (043694645)

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

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

**Establishment**

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

**Establishment**

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

**Establishment**

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

**Establishment**

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

**Establishment**

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

**Establishment**

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