

**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: \_\_\_\_\_

Form 52 005, Rev 0, 8-05-09

**NITROGEN NF LIQUID LABEL**

## **REFRIGERATED LIQUID**

### **NITROGEN, REFRIGERATED LIQUID NF UN1977 NON-FLAMMABLE GAS 2 41977 (R 04/11)**

#### **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.

ALWAYS KEEP CONTAINER IN UPRIGHT POSITION.  
DO NOT CHANGE OR FORCE FIT CONNECTIONS.

#### **WARNING:**

**EXTREMELY COLD LIQUID AND GAS UNDER PRESSURE.  
CAN CAUSE RAPID SUFFOCATION.  
CAN CAUSE SEVERE FROSTBITE.**

Store and use with adequate ventilation.

Do not get liquid in eyes, on skin or clothing.

For liquid withdraw, wear face shield and gloves.

Do not drop. Use suitable hand truck for container movement.

Cylinder temperature should not exceed 52 degrees C (125 degrees F).

Close valve after each use and when empty.

Use a back flow preventive device in the piping.

Use in accordance with the Material Safety Data Sheet (MSDS).

#### **FIRST AID:**

**IF INHALED,** remove to fresh air. If not breathing, give artificial respiration. If breathing, give oxygen.

Call a physician.

**FIRST AID:** IN CASE OF FROSTBITE, obtain medical treatment immediately.

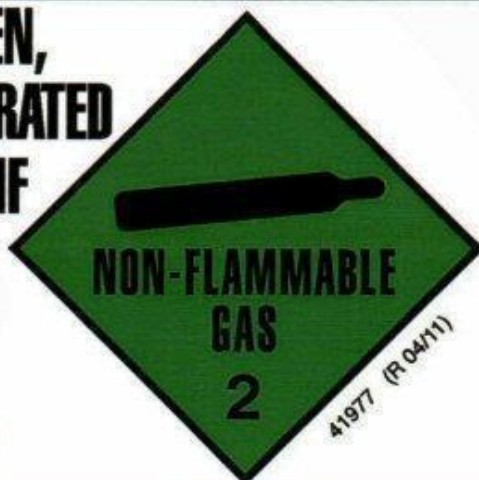
CAS: 7727-37-9

**DO NOT REMOVE THIS PRODUCT LABEL.**

**NORCO** 1125 West Amity Boise, Idaho, 83705 (208) 336-1643  
USPUN1977

# REFRIGERATED LIQUID

**NITROGEN,  
REFRIGERATED  
LIQUID NF**



**UN1977**

**R<sub>x</sub> 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.

↑ **ALWAYS KEEP CONTAINER IN UPRIGHT POSITION.** ↑  
**DO NOT CHANGE OR FORCE FIT CONNECTIONS.**

**WARNING:**

EXTREMELY COLD LIQUID AND GAS UNDER PRESSURE. CAN CAUSE RAPID SUFFOCATION. CAN CAUSE SEVERE FROSTBITE.

Store and use with adequate ventilation.  
Do not get liquid in eyes, on skin or clothing.  
For liquid withdrawal, wear face shield and gloves.  
Do not drop. Use suitable hand truck for container movement.  
Cylinder temperature should not exceed 52°C (125°F).  
Close valve after each use and when empty.  
Use a back flow preventive device in the piping.  
Use in accordance with the Material Safety Data Sheet (MSDS).

**FIRST AID:**

**IF INHALED,** remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

**FIRST AID: IN CASE OF FROSTBITE,** obtain medical treatment immediately.

CAS: 7727-37-9

**DO NOT REMOVE THIS PRODUCT LABEL**



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

USPUN1977

## NITROGEN NF HP LABEL

**NITROGEN COMPRESSED NF UN1066 NON-FLAMMABLE GAS 2 41066 (R 04/11)**

**WARNING:** Secure all cylinders while in storage and in use.

**R<sub>x</sub> 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.

**CAUTION: HIGH PRESSURE GAS. CAN CAUSE RAPID SUFFOCATION.**

Store and use with adequate ventilation. Use a back flow preventive device in the piping. Cylinder temperature should not exceed 52 degrees C (125 degrees F). Close valve after each use and when empty. Use in accordance with the



Material Safety Data Sheet (MSDS).

**FIRST AID: IF INHALED**, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

CAS: 7727-37-9

**DO NOT REMOVE THIS PRODUCT LABEL**

CONTENT \_\_\_\_\_ LOT# \_\_\_\_\_

**NORCO** 1125 W. Amity Rd. Boise, Idaho 83705 (208) 336-1643

USPUN1066

**NITROGEN,  
COMPRESSED  
NF**

**UN1066**

**WARNING:** Secure all cylinders while in storage and in use.

**R<sub>x</sub> 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.

**CAUTION:** HIGH PRESSURE GAS. CAN CAUSE RAPID SUFFOCATION. Store and use with adequate ventilation. Use only with equipment rated for cylinder pressure. Use a back flow preventive device in the piping. Cylinder temperature should not exceed 52°C (125°F). Close valve after each use and when empty. Use in accordance with the MATERIAL SAFETY DATA SHEET (MSDS).

**FIRST AID:** IF INHALED, remove to fresh air. If not breathing, give artificial respiration.

If breathing is difficult, give oxygen. Call a physician.

CAS: 7727-37-9

DO NOT REMOVE THIS PRODUCT LABEL

CONTENT \_\_\_\_\_ LOT # \_\_\_\_\_



1125 W. Amity Rd. • Boise, Idaho 83705  
(208) 336-1643

USPUN1066

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## 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	
<b>Marketing Information</b>				
<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

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)