

OXYGEN - oxygen gas
Norco, Inc.

OXYGEN USP COA

Truck / Trailer# _____



Certificate of Analysis – Oxygen USP

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

For USP 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 USP test results below are completed and, **WHEN DELIVERED TO A PROPERLY FDA REGISTERED USP CUSTOMER**, they are intended to provide a Certificate of Analysis in keeping with current FDA guidance.

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

Test	USP Specification	Lot Analysis
Assay	> 99.0%	
Identification	Pass	
Odor	No appreciable odor	
Carbon Monoxide	≤ 0.001%	*
Carbon Dioxide	≤ 0.003%	*

*Note: The USP compendium exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from required testing for Carbon Dioxide and Carbon Monoxide. Our Oxygen USP is manufactured by the Air Liquefaction Process.

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

Siemens Model Oxyrat 6E

This analyzer has been validated by Norco, Inc. as an acceptable alternative to the official USP Orsat Method for Oxygen Assay. Norco, Inc. maintains validation study documentation at the production location. All other tests (if applicable) performed by compendial methods.

Analysis By: _____ Date: _____

Reviewed & Released By: _____ Date: _____

Form_asu_001 Revision 2 March 7, 2011

OXYGEN COMPRESSED USP LABEL

OXYGEN COMPRESSED USP UN1072 OXYGEN 2 11008LC (R 08/11)

WARNING: For emergency use only when administered by properly trained personnel for Oxygen deficiency and resuscitation. For all other medical applications, **Rx only.** Uninterrupted use of high concentrations of Oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Use only with pressure reducing equipment and apparatus designed for Oxygen. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment. Produced by Air Liquefaction.

WARNING:HIGH PRESSURE OXIDIZING GAS. VIGOROUSLY ACCELERATES COMBUSTION. Keep oil and grease away. Open valve slowly. Store and use with adequate ventilation. Use only with equipment cleaned for Oxygen service and rated for cylinder pressure. Use a back flow preventive device in the piping. Close valve after each use and when empty. Cylinder temperature should not exceed 52 degrees C (125 degrees F). Use in accordance with the **Material Safety Data Sheet (MSDS).**

CAS: 7782-44-7 RETURN WITH 25 PSIG.

DO NOT REMOVE THIS PRODUCT LABEL

NORCO, INC. 1125 W. Amity Road Boise, Id 83705 208-336-1643 USPUN1072

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T 337
J 281
K 249
S 154
DEY 124
Q 90
40 45
R 20
E 24
D 15
C 9
M6 6
E36M 35



OXYGEN REFRIGERATED LIQUID LABEL

REFRIGERATED LIQUID

OXYGEN REFRIGERATE LIQUID USP UN1073 OXYGEN 2 49073 (R 04/11)

WARNING:

For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications Rx only.

Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Use only with pressure reducing equipment and apparatus designed for oxygen. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment.

Produced by Air Liquefaction.

ALWAYS KEEP CONTAINER IN UPRIGHT POSITION.

DO NOT CHANGE OR FORCE FIT CONNECTIONS.

WARNING:

EXTREMELY COLD OXIDIZING LIQUID AND GAS UNDER PRESSURE.

VIGOROUSLY ACCELERATES COMBUSTION.

COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE OR IGNITION OR IMPACT

CAN CAUSE SEVERE FROSTBITE.

Keep oil, grease, and combustibles away. Use only with equipment cleaned for oxygen service. 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. Avoid spills. Do not walk on or roll equipment over spills. 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: IN CASE OF FROSTBITE, obtain medical treatment immediately.

Content:			Lot Batch #		
GP 45	4577	ft ³	31L	940	ft ³
GP 55	5435	ft ³	37L	1124	ft ³
GP 21	3340	ft ³	41L	1245	ft ³
21L	638	ft ³			

CAS: 7782-44-7

DO NOT REMOVE THIS LABEL

Norco 1125 West Amity Boise, Idaho 83705
(208) 336-1643
USPUN1073

REFRIGERATED LIQUID

OXYGEN,
REFRIGERATED
LIQUID
USP
UN1073



WARNING:

For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications **Rx only**.

Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Use only with pressure reducing equipment and apparatus designed for oxygen. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment.

Produced by Air Liquefaction.

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

WARNING:

EXTREMELY COLD OXIDIZING LIQUID AND GAS UNDER PRESSURE. VIGOROUSLY ACCELERATES COMBUSTION. COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT. CAN CAUSE SEVERE FROSTBITE.

Keep oil, grease, and combustibles away. Use only with equipment cleaned for oxygen service. 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. Avoid spills. Do not walk on or roll equipment over spills. 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).

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Content:			Lot Batch #		
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CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL



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

USPUN1073

OXYGEN

oxygen gas

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:42602-001

Route of Administration		RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)			OXYGEN	999 L in 1000 L
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42602-001-01	7051.68 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
2	NDC:42602-001-02	679.68 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
3	NDC:42602-001-03	153919.2 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
4	NDC:42602-001-04	169.92 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
5	NDC:42602-001-05	254.88 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
6	NDC:42602-001-06	424.8 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
7	NDC:42602-001-07	566.4 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
8	NDC:42602-001-08	1132.80 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
9	NDC:42602-001-09	2548.8 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
10	NDC:42602-001-10	3511.68 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
11	NDC:42602-001-11	4361.28 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
12	NDC:42602-001-12	7957.92 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
13	NDC:42602-001-13	9543.84 L in 1 CYLINDER; Type 0: Not a Combination Product	09/01/2008	
14	NDC:42602-001-14	129620.64 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
15	NDC:42602-001-15	94588.8 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
16	NDC:42602-001-16	18068.16 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
17	NDC:42602-001-17	26620.8 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
18	NDC:42602-001-18	31831.68 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
19	NDC:42602-001-19	35258.4 L in 1 DEWAR; Type 0: Not a Combination Product	09/01/2008	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NDA	NDA205820	09/01/2008	
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Labeler - Norco, Inc. (043694645)

Registrant - Norco, Inc. (043694645)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		363348041	manufacture(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		788617470	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		962460528	transfill(42602-001) , manufacture(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		137272659	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		806455218	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		047109152	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		118976116	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		121650725	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		102723566	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		946853975	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		055249275	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		111928342	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		018698922	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		083704353	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		071401038	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		946857844	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		190752779	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		078368984	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		845354000	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		139356232	transfill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco, Inc.		945038586	transfill(42602-001)

Establishment			
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Name	Address	ID/FEI	Business Operations
Norco, Inc.		781691357	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		181115270	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		003202152	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		961763211	manufacture(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		043022300	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		097817373	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		130071848	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		182023523	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		832014042	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		039050695	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco, Inc.		034050950	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		096768908	transfill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		079208258	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		603752429	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		079093441	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		165524927	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		132810735	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		964889302	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		966761629	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		078578534	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		033960626	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		080012315	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		078823016	trans fill(42602-001)

Establishment

Name	Address	ID/FEI	Business Operations
Norco Inc.		831811927	trans fill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		040161353	trans fill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		118976134	trans fill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		066045254	trans fill(42602-001)

Establishment			
Name	Address	ID/FEI	Business Operations
Norco Inc.		081037862	trans fill(42602-001)