## OXYGEN - oxygen gas Air Liquide America Specialty Gases LLC

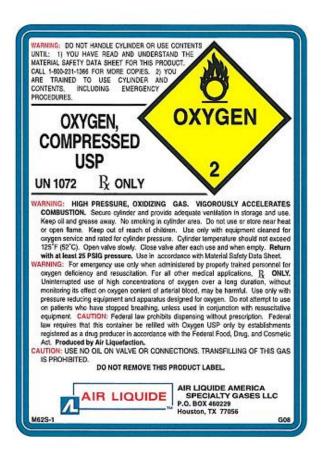
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

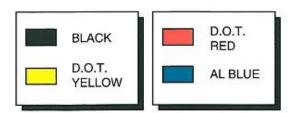
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#### **OXYGEN USP COMPRESSED**

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Enter section text here



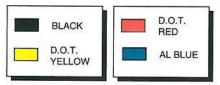


**READ THIS PROOF CAREFULLY** Proof OK as is OK with corrections
New Proof Wanted Downey Decal & Graphics, Inc. 3022 N. Van Buren St., Enid, OK 73701 (580) 237-3434 • Fax (580) 237-6383 West Coast Office: (951) 672-6192 • Fax (951) 672-6194

? FOR PROOF NO. ? DATE SENT

JOB#





#08-10927 AIR LIQUIDE AMERICA SPECIALTY GASES LLC, M61-3, 06-16-08

#### Enter section text here

WARNING: DO NOT HANDLE CYLINDER OR USE CONTENTS UNTIL: 1) YOU HAVE READ AND UNDERSTAND THE MATERIAL SAFETY DATA SHEET FOR THIS PRODUCT. CALL 1-800-231-1366 FOR MORE COPIES. 2) YOU ARE TRAINED TO USE CYLINDER AND CONTENTS, INCLUDING EMERGENCY PROCEDURES.

jmg

WARNING: HIGH PRESSURE, OXIDIZING GAS, VIGOROUSLY ACCELERATES COMBUSTION. Secure cylinder and provide adequate ventilation in storage and use. Keep oil and grease away. No smoking in cylinder area. Do not use or store near heat or open flame. Keep out of reach of children. Use only with equipment cleaned for oxygen service and rated for cylinder pressure. Cylinder temperatures should not exceed 125°F (52°C). Open valve slowly. Close valve after each use and when empty. Return with at least 25 PSIG pressure. Use in accordance with Material Safety Data Sheet.

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.

CAUTION: Federal law prohibits dispensing without prescription. Federal law requires that this container be refilled with Oxygen USP only by establishments registered as a drug producer in accordance with the Federal Food, Drug, and Cosmetic Act. Produced by Air Liquefaction.

CAUTION: USE NO OIL ON VALVE OR CONNECTIONS. TRANSFILLING OF THIS GAS IS PROHIBITED.

DO NOT REMOVE THIS PRODUCT LABEL.

#### **OXYGEN**

oxygen gas

#### **Product Information**

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:42411-010

**Route of Administration** RESPIRATORY (INHALATION)

### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength

Oxygen (UNII: S88TT14065) (Oxygen - UNII:S88TT14065) 99 L in 100 L Oxygen

Packaging								
I	#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
I	1	NDC:42411-010-03	425 L in 1 CYLINDER					

2 NDC:42411-010-01 198 L in 1 CYLINDER 3 NDC:42411-010-02 255 L in 1 CYLINDER 4 NDC:42411-010-04 708 L in 1 CYLINDER 5 NDC:42411-010-08 1558 L in 1 CYLINDER 6 NDC:42411-010-12 3540 L in 1 CYLINDER

7 NDC:42411-010-13 4390 L in 1 CYLINDER

8 NDC:42411-010-20 6514 L in 1 CYLINDER 9 NDC:42411-010-21 7108 L in 1 CYLINDER

**10** NDC:42411-010-22 37212 L in 1 CYLINDER **11** NDC:42411-010-23 42650 L in 1 CYLINDER

**12** NDC:42411-010-25 8609 L in 1 CYLINDER

**13** NDC:42411-010-26 9544 L in 1 CYLINDER

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		0 1/0 1/19 6 0	

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Air Liquide America Specialty Gases LLC		104147434	manufacture		

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Air Liquide America Specialty Gases LLC		146549886	manufacture	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Air Liquide America Specialty Gases LLC		802802587	manufacture	

Establishment					
Name	Address	ID/FEI	Business Operations		
Air Liquide America Specialty Gases LLC		079354007	manufacture		

Establishment					
Name	Address	ID/FEI	Business Operations		
Air Liquide America Specialty Gases LLC		103748765	manufacture		

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Air Liquide America Specialty Gases LLC		803778844	manufacture		

Establishment					
Name	Address	ID/FEI	Business Operations		
Air Liquide America Specialty Gases LLC		134382332	manufacture		

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Air Liquide America Specialty Gases LLC		049087562	manufacture	

Revised: 10/2010 Air Liquide America Specialty Gases LLC