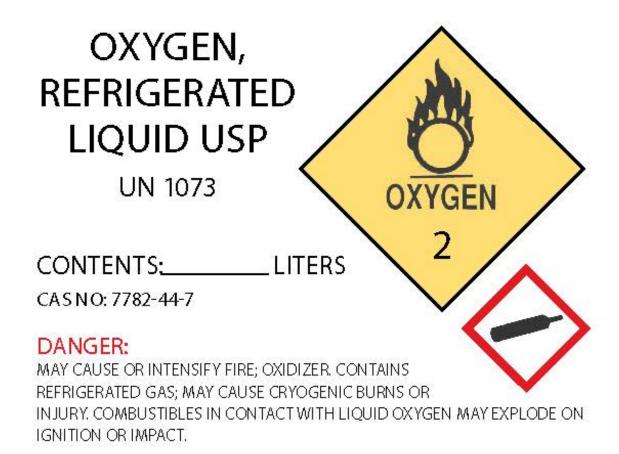
OXYGEN- oxygen gas AeroCare Holdings, LLC

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.

Oxygen

Principal for Oxygen Product



Do not handle until all safety precautions have been read and understood. Keep and store away from do thing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. Wear cold insulating gloves, face shield, and eye protection. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. 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 ON SKIN: <u>Thaw frosted parts with lukewarm water. Do not rub affected</u> area. Get immediate medical advice/attention.

DO NOT REMOVE THIS PRODUCT LABEL.

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. Do not attempt to use on patients who have stopped breathing unless used in conjunction with resuscitative equipment. Produced by Air Liquefaction.

Supplied Home Healthcare Equipment 2014

Representative Labeling pursuant to 21 CFR 207.3 (10)
Company name and contact information are printed in this area

OXYGEN,
REFRIGERATED
LIQUID USP
UN 1073
CONTENTS _____LITERS
CAS NO: 7782-44-7

DANGER:

MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS
REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR
INJURY. COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON
IGNITION OR IMPACT.

Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. Wear cold insulating gloves, face shield, and eye protection. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. 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:

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OXYGEN, COMPRESSED USP UN 1072 DANGER: MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS GAS UNDER PRESSURE:

MAY EXPLODE IF HEATED.

Do not handle until all safety precautions have been read and understood Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. Open valve slowly. 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.

DO NOT REMOVE THIS PRODUCT LABEL.

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. Do not attempt to use on patients who have stopped breathing unless used in conjunction with resuscitative equipment. Produced by Air Liquefaction, shooted Home Healthcare Equipment 2014

Contents Size 113 Liters □ M4 165 Liters □ M6 255 Liters □ C 425 Liters □ D 680 Liters DE 7080 Liters □ H Liters ☐ Other

CAS NO: 7782-44-7

Representative Labeling pursuant to 21 CFR 207.3 (10) Company name and contact information are printed in this box

OXYGEN

COMPRESSED

USP

UN 1072

DANGER:

MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED.

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OXYGEN

oxygen gas

Product Information						
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65551-001			
Route of Administration	RESPIRATORY (INHALATION)					

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	99 L in 100 L			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65551- 001-01	10 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015		
2	NDC:65551- 001-02	21 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015		
3	NDC:65551- 001-03	31 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015		
4	NDC:65551- 001-04	41 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015		
5	NDC:65551- 001-05	46 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015		
6	NDC:65551-	76 L in 1 DEWAR; Type 0: Not a Combination	02/12/2015		

0	001-06	Product	03/17/2013	
7	NDC:65551- 001-07	119 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015	
8	NDC:65551- 001-08	190 L in 1 DEWAR; Type 0: Not a Combination Product	03/12/2015	
9	NDC:65551- 001-09	165 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	
10	NDC:65551- 001-10	255 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	
11	NDC:65551- 001-11	425 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	
12	NDC:65551- 001-12	680 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	
13	NDC:65551- 001-13	1738 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	
14	NDC:65551- 001-14	3455 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	
15	NDC:65551- 001-15	7080 L in 1 CYLINDER; Type 0: Not a Combination Product	03/12/2015	

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
	03/12/2015				
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date			

Labeler - AeroCare Holdings, LLC (135120058)

Establishment			
Name	Address	ID/FEI	Business Operations
AeroCare Holdings, LLC		001304661	manufacture(65551-001)

Establishment			
Name	Address	ID/FEI	Business Operations
AeroCare Holdings, LLC		019549915	manufacture(65551-001)

Establishment			
Name	Address	ID/FEI	Business Operations
AeroCare Holdings, LLC		020033805	manufacture(65551-001)

Establishment					
Name	Address	ID/FEI	Business Operations		
AeroCare Holdings, LLC		022634879	manufacture(65551-001)		

Establishment			
Name	Address	ID/FEI	Business Operations
AeroCare Holdings, LLC		071339981	manufacture(65551-001)

Establishment			
Name	Address	ID/FEI	Business Operations
AeroCare Holdings, LLC		078444694	manufacture(65551-001)

Establishment			
Name	Address	ID/FEI	Business Operations
AeroCare Holdings, LLC		078821982	manufacture(65551-001)

Establishment					
Name	Address	ID/FEI	Business Operations		
AeroCare Holdings, LLC		790141043	manufacture(65551-001)		

Establishment					
Name	Address	ID/FEI	Business Operations		
AeroCare Holdings, LLC		959580002	manufacture(65551-001)		

Revised: 4/2024 AeroCare Holdings, LLC