OXYGEN- oxygen gas Sanford HealthCare Accessories, 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, USP

Principal for Oxygen Product



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.

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.

CAS NO: 7782-44-7

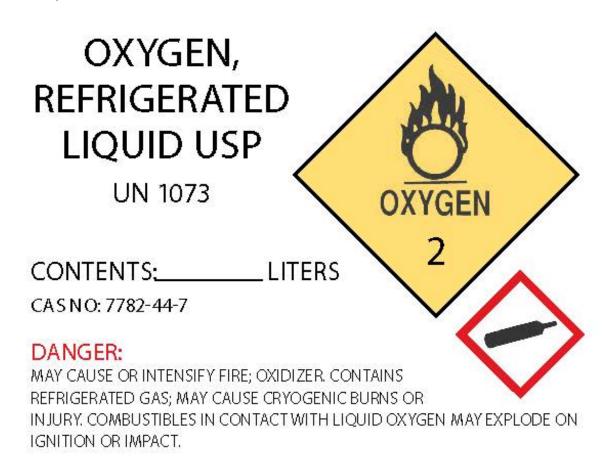
DO NOT REMOVE THIS PRODUCT LABEL.

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.



Do not handle until all safety precautions have been read and understood.

Keep and store away from dothing 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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Representative Labeling pursuant to 21 CFR 207.3 (10)

OXYGEN

oxygen gas

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57993-001
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			

Pa	Packaging						
#	# Item Code Package Description		Marketing Start Date	Marketing End Date			
1	NDC:57993- 001-01	164 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
2	NDC:57993- 001-02	248 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
3	NDC:57993- 001-03	425 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
4	NDC:57993- 001-04	684 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
5	NDC:57993- 001-05	3454 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
6	NDC:57993- 001-06	6910 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
7	NDC:57993- 001-10	640 L in 1 CYLINDER; Type 0: Not a Combination Product	10/26/2010				
8	NDC:57993- 001-11	230 L in 1 DEWAR; Type 0: Not a Combination Product	10/26/2010				

9	NDC:57993- 001-12	41 L in 1 DEWAR; Type 0: Not a Combination Product	10/26/2010
10	NDC:57993- 001-13	21 L in 1 DEWAR; Type 0: Not a Combination Product	10/26/2010

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved medical gas		10/26/2010			

Labeler - Sanford HealthCare Accessories, LLC (147581557)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		021949898	manufacture(57993-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		078813704	manufacture(57993-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		078813711	manufacture(57993-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		147581557	manufacture(57993-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		612629683	manufacture(57993-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		790120224	manufacture(57993-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Sanford Healthcare Accessories, LLC		961930158	manufacture(57993-001)	

Establishment					
Name	Address	ID/FEI	Business Operations		
Sanford Healthcare Accessories, LLC		961930216	manufacture(57993-001)		

Establishment					
Name	Address	ID/FEI	Business Operations		
Sanford Healthcare Accessories Bemidji		969675367	manufacture(57993-001)		

Revised: 11/2023 Sanford HealthCare Accessories, LLC