

OXYGEN- oxygen gas
Rotech Healthcare Inc

Oxygen

OXYGEN, COMPRESSED USP

UN1072

PRODUCED BY AIR LIQUEFACTION.

WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx required. 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. Keep out of reach of children. Federal law requires that this container be refilled with oxygen USP only by establishments registered as a drug manufacturer in accordance with the Federal Food, Drug and Cosmetic Act. DANGER: MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. Obtain, read and follow all safety instructions before use. Keep 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. Close valve after each use and when empty. Use only with equipment rated for cylinder pressure. Do not open valve until connected to equipment prepared for use. Use only equipment of compatible materials of construction. Open valve slowly. Use only with equipment cleaned for oxygen service. Protect from sunlight when ambient temperature exceeds 52 C (125 F). Read and follow the Safety Data Sheet (SDS) before use. CAS 7782-44-7 DO NOT REMOVE THIS PRODUCT LABEL.

NO SMOKING

NO VAPING



OXYGEN, REFRIGERATED LIQUID USP

UN1073

PRODUCED BY AIR LIQUEFACTION

WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx required. 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. Keep out of reach of children. Federal law requires that this container be refilled with oxygen USP only by establishments registered as a drug manufacturer in accordance with the Federal Food, Drug, and Cosmetic Act.

DANGER: MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY. COMBUSTIBLES IN CONTACT WITH OXIDIZING REFRIGERATED LIQUIDS MAY EXPLODE ON IGNITION OR IMPACT. Obtain, read and follow all safety instructions before use. Keep 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 and either face shield or eye protection. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Close valve after each use and when empty. Use only with equipment rated for cylinder pressure. Do not open valve until connected to equipment prepared for use. Use only equipment of compatible materials of construction. Open valve slowly. Use only with equipment cleaned for oxygen service. Always keep container in upright position. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. Read and follow all Safety Data Sheet (SDS) before use.

FIRST AID: IF ON SKIN: Immediately thaw frosted parts with lukewarm water. Do not rub

affected area. Get medical help. CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL.



OXYGEN

oxygen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57439-005
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	990 mL in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57439-005-08	3455 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
2	NDC:57439-005-09	7100 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
3	NDC:57439-005-10	9430 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
4	NDC:57439-005-01	113 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
5	NDC:57439-005-02	170 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	

6	NDC:57439-005-03	255 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
7	NDC:57439-005-04	425 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
8	NDC:57439-005-05	680 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
9	NDC:57439-005-06	1738 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
10	NDC:57439-005-07	2549 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
11	NDC:57439-005-11	20 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	
12	NDC:57439-005-12	30 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	
13	NDC:57439-005-13	32 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	
14	NDC:57439-005-14	37 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	
15	NDC:57439-005-15	45 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205889	01/01/2018	

Labeler - Rotech Healthcare Inc (144556222)

Registrant - Rotech Healthcare Inc (144556222)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		016953296	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
RHEMA MEDICAL		078670599	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Plus, Inc. dba Summit Respiratory		079569918	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
HEARTLAND HOME HEALTH CARE		079570162	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

ROTECH		079570216	manufacture(57439-005)
--------	--	-----------	------------------------

Establishment

Name	Address	ID/FEI	Business Operations
MAJOR MEDICAL		079607390	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		079607401	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
COMMUNITY HOME OXYGEN		079607617	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH HOME MEDICAL CARE		079607622	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
FIRST CARE		079639101	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
CARE MEDICAL SUPPLIES, INC. dba Rotech of Arlington Heights		079713679	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		079721579	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
MAJOR MEDICAL SUPPLY		079721904	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		079738728	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
KELLEY'S HOME HEALTH SERVICES		079738768	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
G&G MEDICAL		085400138	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
RESPONSIVE HOME HEALTH CARE, INC. dba ROTECH		098136096	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
SUMMIT RESPIRATORY		135922784	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
CPO2		148713329	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
HOME CARE MEDICAL SERVICES		169932436	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
Sentry Home Health		174392501	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
ROTH MEDICAL		179387050	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
CAMBRIA MEDICAL SUPPLY		620007021	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
HOME MEDICAL SYSTEMS		795469142	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
Community Home Oxygen, Inc.		796500432	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
SUMMIT RESPIRATORY		831552372	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
MMS Norfolk, Inc.		797232907	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

ROTH MEDICAL		831552364	manufacture(57439-005)
--------------	--	-----------	------------------------

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		831562918	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
FAMILY HOME CARE		831748491	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
GREAT LAKES HOME MEDICAL		831831172	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
MED-AIR TRANSFILL		841973667	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
ROTH MEDICAL		948744180	manufacture(57439-005)

Establishment

Name	Address	ID/FEI	Business Operations
VITALCARE HEALTH SERVICES		956721187	manufacture(57439-005)

Revised: 12/2025

Rotech Healthcare Inc