

OXYGEN- oxygen gas
Rotech Healthcare Inc

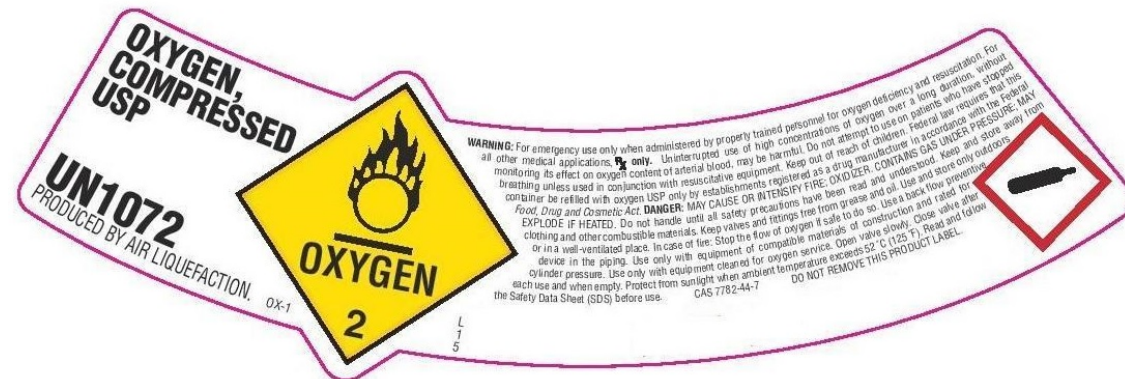
Oxygen

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 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. 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.** 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. 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 7782-44-7 **DO NOT REMOVE THIS PRODUCT LABEL.**



OXYGEN, REFRIGERATED LIQUID USP

UN1073

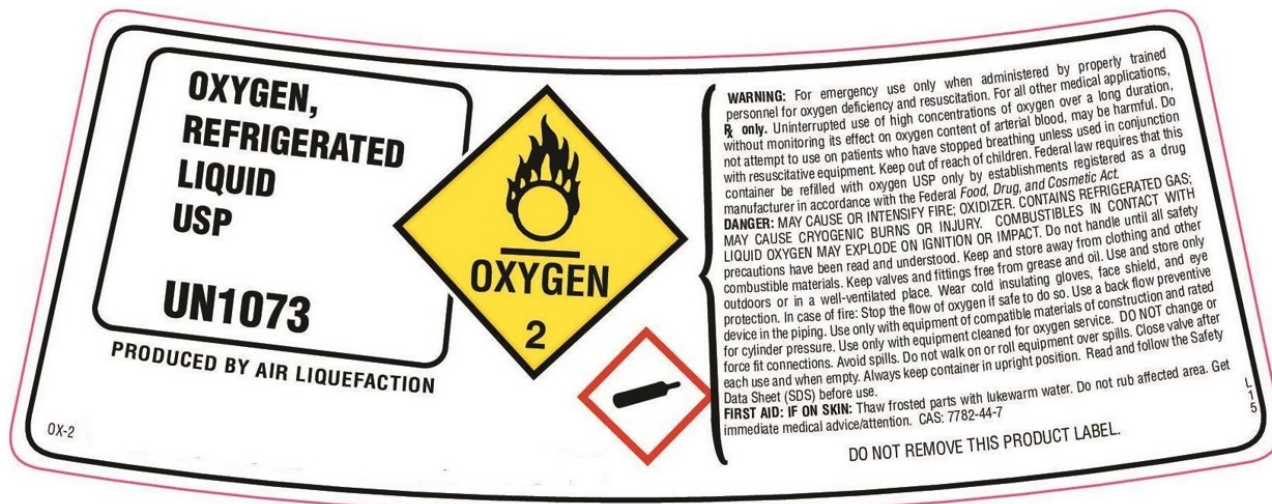
PRODUCED BY AIR LIQUEFACTION

WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx 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. 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 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 well-ventilated place. Wear cold insulating gloves, face shield, and eye protection. In case of fire: Stop the flow of oxygen 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: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention. CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL



OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:57439-003 |
| 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:57439-003-08 | 3455 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 2 | NDC:57439-003-09 | 7100 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 3 | NDC:57439-003-10 | 9430 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 4 | NDC:57439-003-01 | 113 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 5 | NDC:57439-003-02 | 170 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 6 | NDC:57439-003-03 | 255 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 7 | NDC:57439-003-04 | 425 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 8 | NDC:57439-003-05 | 680 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 9 | NDC:57439-003-06 | 1738 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 10 | NDC:57439-003-07 | 2549 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/2018 | |
| 11 | NDC:57439-003-11 | 20 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/2018 | |
| 12 | NDC:57439-003-12 | 30 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/2018 | |
| 13 | NDC:57439-003-13 | 32 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/2018 | |
| 14 | NDC:57439-003-14 | 37 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/2018 | |
| 15 | NDC:57439-003-15 | 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(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|------------------------|
| RHEMA MEDICAL | | 078670599 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Oxygen Plus, Inc. dba Summit Respiratory | | 079569918 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| HEARTLAND HOME HEALTH CARE | | 079570162 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 079570216 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|------------------------|
| MAJOR MEDICAL | | 079607390 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 079607401 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| COMMUNITY HOME OXYGEN | | 079607617 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| ROTECH HOME MEDICAL CARE | | 079607622 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|------------------------|
| FIRST CARE | | 079639101 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| ROTECH OF ARLINGTON HEIGHTS | | 079713679 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 079721579 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| MAJOR MEDICAL SUPPLY | | 079721904 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 079738728 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------|
| KELLEY'S HOME HEALTH SERVICES | | 079738768 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| G&G MEDICAL | | 085400138 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 098136096 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| SUMMIT RESPIRATORY | | 135922784 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|-----------|------------------------|
| CPO2 | | 148713329 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 159346050 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| HOME CARE MEDICAL SERVICES | | 169932436 | manufacture(57439-003) |

Establishment

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

| | | | |
|--------------------|--|-----------|------------------------|
| Sentry Home Health | | 174392501 | manufacture(57439-003) |
|--------------------|--|-----------|------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| ROTH MEDICAL | | 179387050 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 611480690 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| CAMBRIA MEDICAL SUPPLY | | 620007021 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| HOME MEDICAL SYSTEMS | | 795469142 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| SENTRY HOME HEALTH | | 796502123 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| G&G MEDICAL | | 796502479 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| ROTH MEDICAL | | 831552364 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| SUMMIT RESPIRATORY | | 831552372 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 831562918 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| FAMILY HOME CARE | | 831748491 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| GREAT LAKES HOME MEDICAL | | 831831172 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| ROTECH | | 833186922 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| MED-AIR TRANSFILL | | 841973667 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| SUMMIT RESPIRATORY | | 874476422 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| ROTH MEDICAL | | 948744180 | manufacture(57439-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| VITALCARE HEALTH SERVICES | | 956721187 | manufacture(57439-003) |

Revised: 6/2022

Rotech Healthcare Inc