

OXYGEN- oxygen gas
Advanced Home Care

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

| <p>DANGER: MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED.</p>  <p>C.A.S. NO. 7782-44-7</p> <p>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.</p> |  <p>ADVANCED HOME CARE 4001 PIEDMONT PARKWAY HIGH POINT, NC 27265 (800) 868-8822</p> <p>OXYGEN, COMPRESSED USP UN1072</p> <p>PRODUCED BY AIR LIQUEFACTION</p> | <table border="1"> <thead> <tr> <th>SIZE</th> <th>CONTENTS</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> M6 165 LTRS.</td> <td>2216 PSI AT 70°F</td> </tr> <tr> <td><input type="checkbox"/> D 359 LTRS.</td> <td>2000 PSI AT 70°F</td> </tr> <tr> <td><input type="checkbox"/> E 655 LTRS.</td> <td>2000 PSI AT 70°F</td> </tr> <tr> <td><input type="checkbox"/> M60 1699 LTRS.</td> <td>2216 PSI AT 70°F</td> </tr> <tr> <td><input type="checkbox"/> MM 3450 LTRS.</td> <td>2216 PSI AT 70°F</td> </tr> </tbody> </table> <p>DO NOT REMOVE THIS PRODUCT LABEL.</p> <p>DANGER: 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. 46180 (05/15)</p> | SIZE | CONTENTS | <input type="checkbox"/> M6 165 LTRS. | 2216 PSI AT 70°F | <input type="checkbox"/> D 359 LTRS. | 2000 PSI AT 70°F | <input type="checkbox"/> E 655 LTRS. | 2000 PSI AT 70°F | <input type="checkbox"/> M60 1699 LTRS. | 2216 PSI AT 70°F | <input type="checkbox"/> MM 3450 LTRS. | 2216 PSI AT 70°F |
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| <input type="checkbox"/> MM 3450 LTRS. | 2216 PSI AT 70°F | | | | | | | | | | | | | |

Liquid Label

| | | |
|--|--|---|
|  <p>4001 PIEDMONT PARKWAY HIGH POINT, NC 27265 (800) 868-8822</p> <p>OXYGEN, REFRIGERATED LIQUID USP</p> <p>UN1973</p> <p>GAS: 7782-44-7</p> <p>Rx ONLY.</p> <p>DO NOT REMOVE THIS PRODUCT LABEL.</p> |  <p>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.</p> <p>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.</p> <p>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.</p> <p>FIRST AID: IF ON SKIN: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.</p> <p>PRODUCED BY AIR LIQUEFACTION.</p> <p>TO BE FILLED BY A MEDICAL GAS FACILITY ONLY.</p> | <p>Contents (Volume) / Model 21 liter/21a 31 liter/31a 41 liter/41a</p>  <p>17510 (05/15)</p> |
|--|--|---|

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:558 13-123 |
| 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:558 13-123-02 | 425 L in 1 CYLINDER; Type 0: Not a Combination Product | 10/27/20 15 | |
| 2 | NDC:558 13-123-03 | 682 L in 1 CYLINDER; Type 0: Not a Combination Product | 10/27/20 15 | |
| 3 | NDC:558 13-123-04 | 1738 L in 1 CYLINDER; Type 0: Not a Combination Product | 10/27/20 15 | |
| 4 | NDC:558 13-123-05 | 3455 L in 1 CYLINDER; Type 0: Not a Combination Product | 10/27/20 15 | |
| 5 | NDC:558 13-123-06 | 46 L in 1 DEWAR; Type 0: Not a Combination Product | 10/27/20 15 | |
| 6 | NDC:558 13-123-01 | 165 L in 1 CYLINDER; Type 0: Not a Combination Product | 10/27/20 15 | |
| 7 | NDC:558 13-123-07 | 36 L in 1 DEWAR; Type 0: Not a Combination Product | 10/27/20 15 | |
| 8 | NDC:558 13-123-08 | 21 L in 1 DEWAR; Type 0: Not a Combination Product | 10/27/20 15 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved medical gas | | 10/27/20 15 | |

Labeler - Advanced Home Care (603161209)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|-------------------------|
| Advanced Home Care, Inc. | | 008930102 | manufacture(558 13-123) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| Advanced Home Care, Inc | | 031557958 | manufacture(558 13-123) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|-------------------------|
| Advanced Home Care, Inc. | | 073459898 | manufacture(558 13-123) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| Advanced Home Care, Inc | | 078652894 | manufacture(558 13-123) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|-------------------------|
| Advanced Home Care, Inc. | | 078818616 | manufacture(558 13-123) |

| Establishment | | | |
|--------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Advanced Home Care, Inc. | | 079708390 | manufacture(55813-123) |

| Establishment | | | |
|--------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Advanced Home Care, Inc. | | 118915730 | manufacture(55813-123) |

| Establishment | | | |
|--------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Advanced Home Care, Inc. | | 603161209 | manufacture(55813-123) |

| Establishment | | | |
|-------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Advanced Home Care, Inc | | 620931506 | manufacture(55813-123) |

| Establishment | | | |
|-------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Advanced Home Care, Inc | | 828372693 | manufacture(55813-123) |

Revised: 11/2015

Advanced Home Care