

**HELIUM OXYGEN MIXTURE- helium oxygen mixture gas
Linde Gas & Equipment Inc.**

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.

Helium Oxygen Mixture

UN3156

COMPRESSED GAS,

OXIDIZING, N.O.S.

(OXYGEN, HELIUM)

% HELIUM USP LOT NUMBER

% OXYGEN USP NET CONTENTS

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/Store away from clothing and other combustible materials. Keep reduction valves/valves and fittings from oil and grease. IN CASE OF FIRE: Stop leak if safe to do so. Use and store only outdoors or in a well-ventilated place. Use a back flow preventative device in the piping. Use only with equipment rated for cylinder pressure. Do not open valve until connected to equipment prepared for use. Close valve after each use and when empty. Protect from sunlight when ambient temperature exceeds 52°C (125°F). Open valve slowly. Use only equipment cleaned for oxygen service. Read and follow the Safety Data Sheet (SDS) before use.

WARNING: Administration of this gas mixture may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of gas mixtures and is familiar with the indications, effects, dosages, methods and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken.

Rx only

IN CASE OF EMERGENCY CALL 1-800-645-4633

CAS: (7782-44-7) (7440-59-7)

Medipure By Linde

MDB-0075 (Rev. 01) DO NOT REMOVE THIS LABEL DISTRIBUTED BY LINDE, INC.
DANBURY, CT 06810-6268

UN3156

COMPRESSED GAS, OXIDIZING, N.O.S.
(OXYGEN, HELIUM)



COMPONENTS:

_____ % HELIUM USP

LOT NUMBER _____

_____ % OXYGEN USP

NET CONTENTS _____

DANGER!

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Medipure
By Linde

Linde

MDB-0075 (Rev. 01)

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DANBURY, CT 06810-6268

HELIUM OXYGEN MIXTURE

helium oxygen mixture gas

Product Information

| | | | |
|-------------------------|--------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59579-009 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| HELIUM (UNII: 206GF3GB41) (HELIUM - UNII:206GF3GB41) | HELIUM | 800 mL in 1 L |
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 200 mL in 1 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59579-009-01 | 7900 L in 1 CYLINDER; Type 0: Not a Combination Product | 08/01/2007 | |
| 2 | NDC:59579-009-02 | 5975 L in 1 CYLINDER; Type 0: Not a Combination Product | 08/01/2007 | |
| 3 | NDC:59579-009-03 | 2010 L in 1 CYLINDER; Type 0: Not a Combination Product | 08/01/2007 | |
| 4 | NDC:59579-009-04 | 963 L in 1 CYLINDER; Type 0: Not a Combination Product | 08/01/2007 | |
| 5 | NDC:59579- | 595 L in 1 CYLINDER; Type 0: Not a Combination | 08/01/2007 | |

| | | | | |
|----|------------------|---|------------|--|
| 5 | 009-05 | Product | 08/01/2007 | |
| 6 | NDC:59579-009-06 | 368 L in 1 CYLINDER; Type 0: Not a Combination Product | 08/01/2007 | |
| 7 | NDC:59579-009-07 | 3086 L in 1 CYLINDER; Type 0: Not a Combination Product | 09/01/2020 | |
| 8 | NDC:59579-009-08 | 509 L in 1 CYLINDER; Type 0: Not a Combination Product | 09/01/2020 | |
| 9 | NDC:59579-009-09 | 3822 L in 1 CYLINDER; Type 0: Not a Combination Product | 09/01/2020 | |
| 10 | NDC:59579-009-10 | 3822 L in 1 CYLINDER; Type 0: Not a Combination Product | 09/01/2020 | |
| 11 | NDC:59579-009-11 | 623 L in 1 CYLINDER; Type 0: Not a Combination Product | 09/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved medical gas | | 08/01/2007 | |

Labeler - Linde Gas & Equipment Inc. (042845636)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Linde Gas & Equipment Inc. | | 161317490 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Linde Gas & Equipment Inc. | | 044574523 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Linde Gas & Equipment Inc. | | 045252439 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Linde Gas & Equipment Inc. | | 196953322 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Linde Gas & Equipment Inc. | | 948364559 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Linde Gas & Equipment Inc. | | 080185766 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|----------------|---------------|----------------------------|
| Linde Gas & Equipment Inc. | | 027514424 | manufacture(59579-009) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|----------------|---------------|----------------------------|
| Linde Gas & Equipment Inc. | | 148052277 | manufacture(59579-009) |

Revised: 1/2025

Linde Gas & Equipment Inc.