HELIUM- helium gas Linde Gas & Equipment Inc.

Helium - Human

UN1046 HELIUM, COMPRESSED USP

WARNING! CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. MAY DISPLACE

OXYGEN AND CAUSE RAPID SUFFOCATION. Do not handle until all safety precautions have been read and understood.

Use and store only outdoors or in a well-ventilated place. Use a back flow preventive 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. Do not inhale for recreational use. Protect from sunlight when ambient temperature exceeds 52°C (125°F). Read and follow the Safety Data Sheet (SDS) before use.

FIRST AID: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Get medical advice/attention. **WARNING:** Administration of helium 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

helium 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: 7440-59-7

Medipure By Linde

Linde

DO NOT REMOVE THIS LABEL MDS-0003 (Rev. 01)

DISTRIBUTED BY LINDE INC., DANBURY, CT 06810-6268



HELIUM

helium gas

| Product Information | | | |
|----------------------------|--------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59579-005 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

| Active Ingredient/Active Moiety | | |
|--|--------------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| HELIUM (UNII: 206GF3GB41) (HELIUM - UNII:206GF3GB41) | HELIUM | 990 mL in 1 L |

| Pa | Packaging | | | | |
|----|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:59579- 005-01 | 14696 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 2 | NDC:59579- 005-02 | 12233 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 3 | NDC:59579- 005-03 | 9430 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 4 | NDC:59579- 005-04 | 8240 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 5 | NDC:59579- 005-05 | 6909 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 6 | NDC:59579- 005-06 | 6173 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 7 | NDC:59579- 005-07 | 3823 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 8 | NDC:59579- 005-08 | 3087 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |
| 9 | NDC:59579- 005-09 | 2067 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | | |

| 10 | NDC:59579- 005-10 | 1048 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
|----|----------------------|---|------------|--|
| 11 | NDC:59579- 005-11 | 623 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 12 | NDC:59579- 005-12 | 510 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 13 | NDC:59579- 005-15 | 368 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 14 | NDC:59579- 005-16 | 113 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 15 | NDC:59579- 005-17 | 170 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 16 | NDC:59579- 005-18 | 6768 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 17 | NDC:59579- 005-19 | 2209 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 18 | NDC:59579- 005-20 | 821 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 19 | NDC:59579- 005-13 | 538 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 20 | NDC:59579- 005-14 | 142 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/01/2007 | |
| 21 | NDC:59579- 005-21 | 99 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/09/2020 | |
| 22 | NDC:59579- 005-22 | 99 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/09/2020 | |
| 23 | NDC:59579- 005-23 | 57 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/09/2020 | |
| 24 | NDC:59579- 005-24 | 3820 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/09/2020 | |
| 25 | NDC:59579- 005-25 | 396 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/09/2020 | |
| 26 | NDC:59579- 005-26 | 1444 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/09/2020 | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| NDA | NDA205912 | 12/01/2007 | | |
| | | | | |

Labeler - Linde Gas & Equipment Inc. (042845636)

| Establishment | | | |
|----------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Linde Gas & Equipment Inc. | | 161317490 | manufacture(59579-005) |

| Establishment | | | |
|----------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Linde Gas & Equipment Inc. | | 045252439 | manufacture(59579-005) |

Establishment

| Hunc | Addiess | 10/1 L1 | business operations |
|----------------------------|---------|-----------|----------------------------|
| Linde Gas & Equipment Inc. | | 159890391 | manufacture(59579-005) |
| | | | |
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Linde Gas & Equipment Inc. | | 049964372 | manufacture(59579-005) |
| | | | |
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Linde Gas & Equipment Inc. | | 027514424 | manufacture(59579-005) |
| | | | |
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Linde Gas & Equipment Inc. | | 080185766 | manufacture(59579-005) |
| | | | |
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Linde Gas & Equipment Inc. | | 196953322 | manufacture(59579-005) |
| | | | |
| Establishment | | | |

ID/FEI

Business Operations

Business Operations

manufacture(59579-005)

Address

Name

Name

Linde Gas & Equipment Inc.

Revised: 1/2025 Linde Gas & Equipment Inc.

ID/FEI

948364559

Address