

HELIUM- helium gas
Roberts Oxygen Company, Inc.

Helium-008

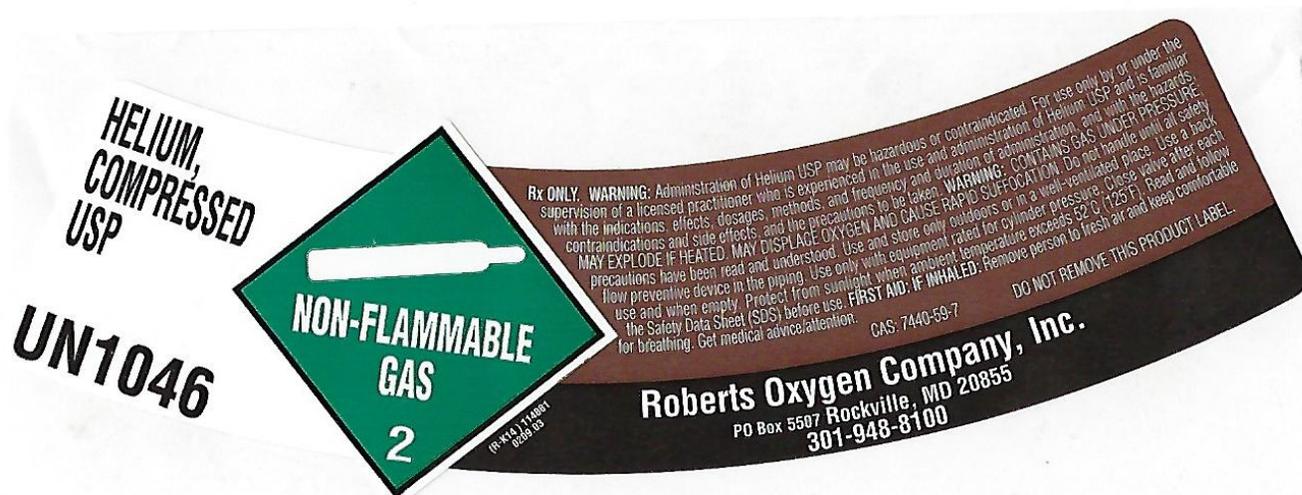
**HELIUM,
 COMPRESSED
 USP
 UN1046**

NON-FLAMMABLE GAS 2

Rx ONLY. WARNING: Administration of Helium USP 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 USP and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and the hazards, contraindications and side effects and the precautions to be taken. **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 preventative device in the piping. Use only with equipment rated for cylinder pressure. 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. **FIRST AID: IF INHALED:** Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention.

CAS: 7440-59-7 DO NOT REMOVE THIS PRODUCT LABEL.

Roberts Oxygen Company, Inc.
 PO BOX 5507 Rockville, MD 20855
 301-948-8100



HELIUM			
helium gas			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:46 123-008
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46123-008-01	102 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	
2	NDC:46123-008-02	374 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	
3	NDC:46123-008-03	623 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	
4	NDC:46123-008-04	3880 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	
5	NDC:46123-008-05	5436 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	
6	NDC:46123-008-06	6910 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	
7	NDC:46123-008-07	8241 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/1967	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205864	01/01/1967	

Labeler - Roberts Oxygen Company, Inc. (042646877)**Establishment**

Name	Address	ID/FEI	Business Operations
Roberts Oxygen Company, Inc.		791818008	manufacture(46123-008)

Revised: 11/2020

Roberts Oxygen Company, Inc.