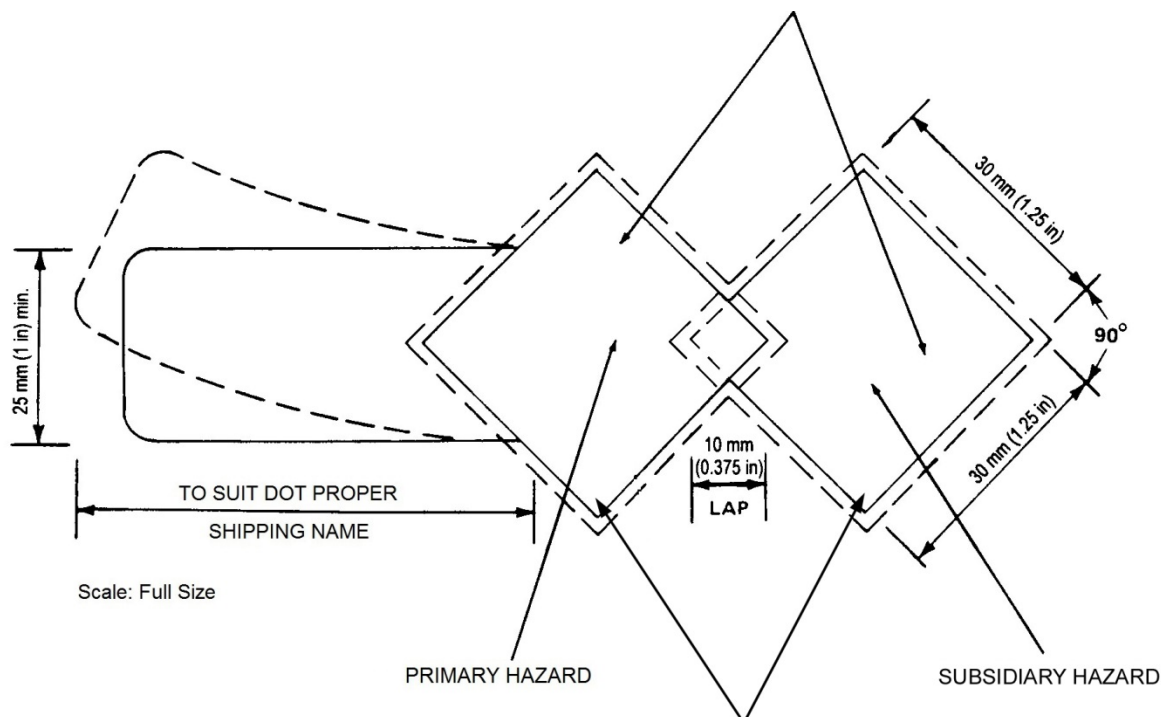


The basic marking in Figure A-2 illustrates an example when an additional diamond is added to denote the subsidiary hazard when required by 49 CFR 172.101 or TC regulations [3, 4]. The primary hazard diamond overlaps the subsidiary hazard.

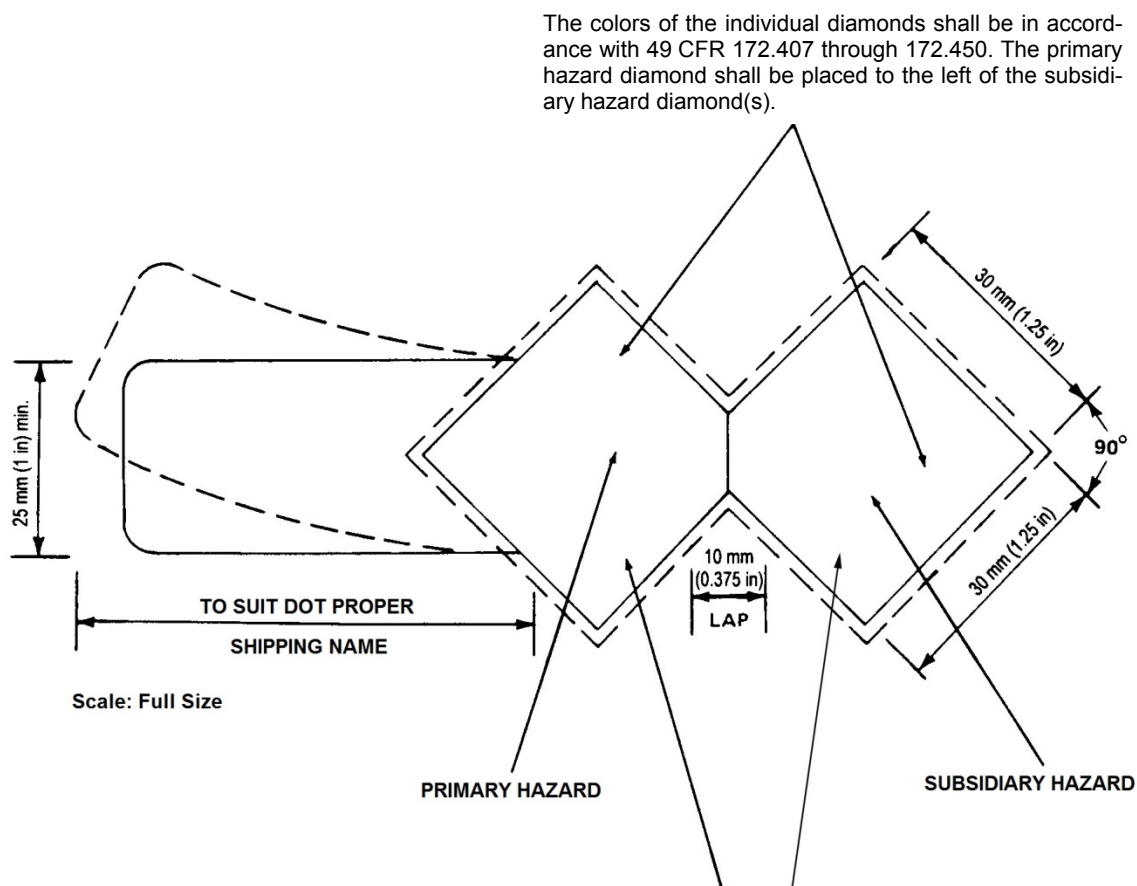
The colors of the individual diamonds shall be in accordance with 49 CFR 172.407 through 172.450 or TC regulations. The primary hazard diamond shall be placed to the left of the subsidiary hazard diamond(s).



The hazard class number shall appear in both the primary and subsidiary hazard diamond symbols.

Figure A-2—Basic markings for multiple hazard diamonds (overlapped)

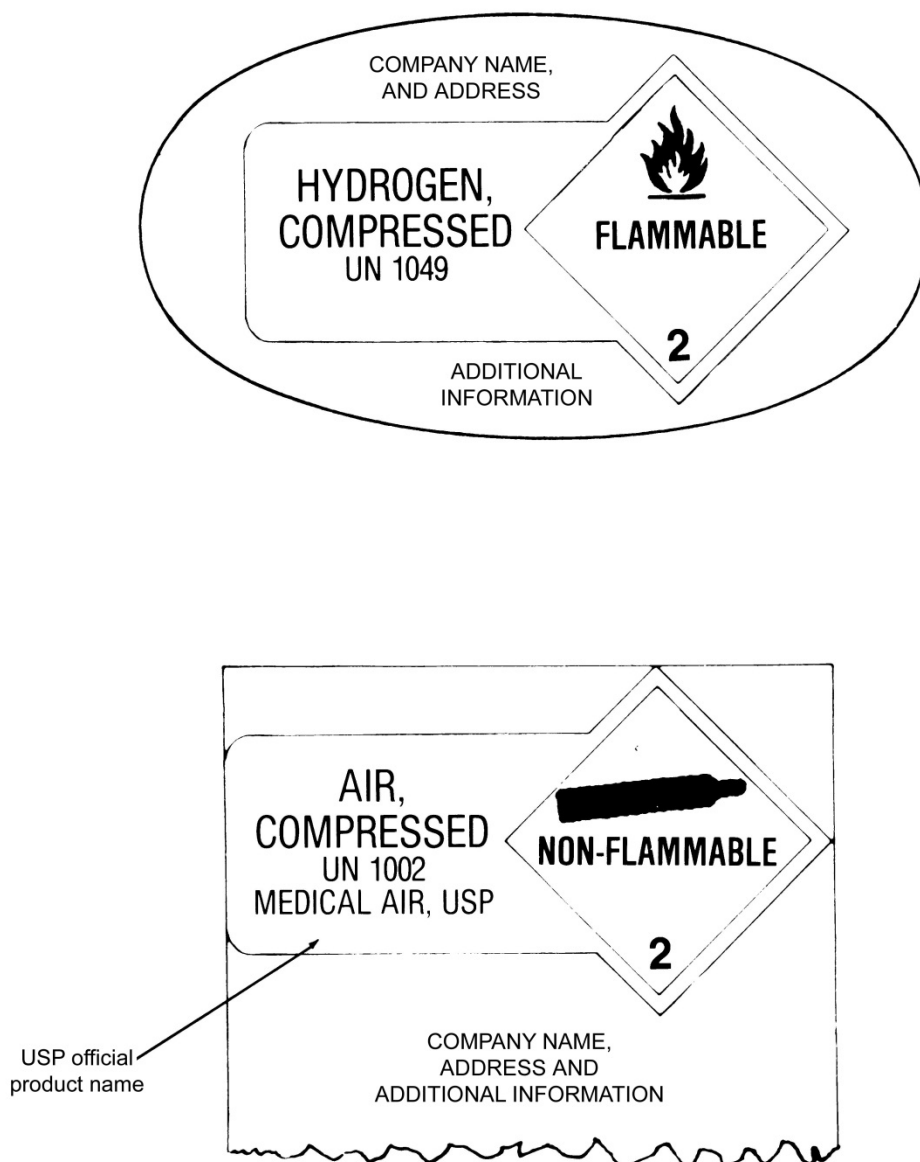
The basic marking in Figure A-3 illustrates an example when an additional diamond is added to denote the subsidiary hazard when required by 49 CFR 172.101 [3]. The primary and subsidiary hazard diamonds are truncated with the primary hazard diamond always on the left.



The hazard class number shall appear in both the primary and subsidiary hazard diamond symbols.

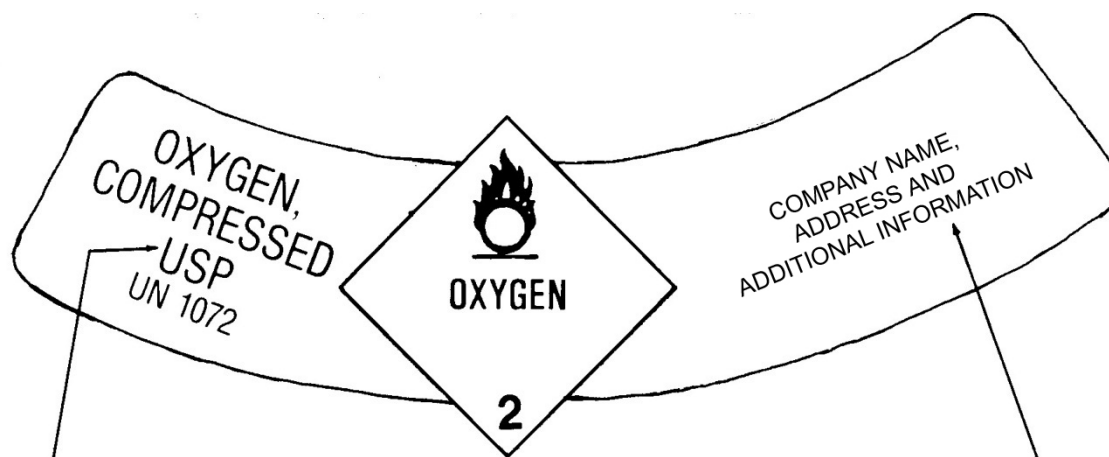
NOTE—For shipments within the United States or to Canada that originate in the United States, truncating of the diamonds is permitted.

Figure A-3—Basic markings for multiple hazard diamonds (truncated)



NOTE—When required by FDA or HPFBI, the official product name including the USP/NF designation is allowed to appear directly above, below, or beside the proper shipping name in the panel or elsewhere on the label.

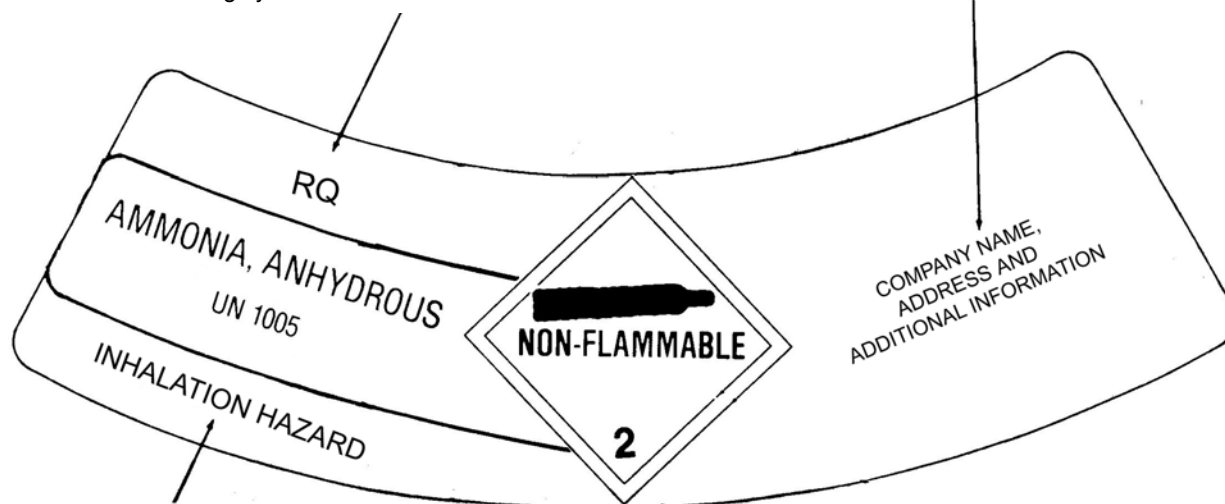
Figure A-4—Examples of CGA marking system
(not to scale)



When the USP/NF markings are required by FDA or HPFBI, they are allowed to be displayed in the left panel.

This portion of the label may be used to display the additional information required by FDA, OSHA, or HPFBI.

In the United States, if RQ is required, it shall be printed in association with the proper shipping name in letters not less than 2 mm (0.0625 in) in height. This information may appear in the panel or elsewhere in the CGA marking system.



In the United States, the words INHALATION HAZARD shall be printed in association with the proper shipping name and be at least 2 mm (0.0625 in) in height. This information may appear in the panel or elsewhere in the CGA marking system.

Figure A-5—Examples of CGA marking system for U.S. domestic shipment of oxygen and ammonia as described in A.4
(not to scale)

Appendix B—CGA labeling guide for compressed medical gases classified as drugs (Normative)

This appendix was revised to be consistent with the labeling requirements of Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 201 and current industry practices as they apply to the labeling of those compressed medical gases classified as drugs [9].

The information in this guide is intended as an aid in complying with the applicable FDA regulations for the labeling of medical gases classified as drugs. This guide contains what is considered to be the minimum requirements for medical gas labels and might not contain all language necessary to comply with FDA regulations. It is the responsibility of the gas supplier to assure that the labels and markings comply with all applicable government regulations (DOT, EPA, OSHA, TC, etc.). This guide should be used in conjunction with other applicable labeling and marking information contained in this publication, specifically, Appendix A and applicable illustrative labels in Section 9.

The phrases presented as material handling warnings and precautions, (i.e., not the Warning statement that begins with “Administration of ...”) in the medical gas mixtures illustrative labels in this appendix are directed to the persons who are handling or administering the gas and not the person to whom the gas may ultimately be administered.

Unless an asterisk notes an exception, the GHS and CGA phrases shown on the illustrative labels in this appendix are required.

B.1 CGA definition of terms

Manufacturer—Any person or firm who produces, fills, repackages (transfills), or relabels medical drug gas cylinders.

Distributor—Any person or firm who markets filled medical drug gas cylinders and who has not performed any manufacturing steps such as filling, repackaging, or relabeling.

B.2 General requirements

All medical drug gas labels shall bear the:

- Name and address of the manufacturer or distributor. Where the medical gas distributor’s name appears on the label, the distributor’s name shall be qualified by one of the following phrases:
 - “Manufactured for (name)”
 - “Distributed by (name)”
 - “Manufactured by (name) for (name)”
 - “Manufactured for (name) by (name)”
 - “Distributor: (name)” or
 - “Marketed by (name)”;

NOTE—If cylinders are owned by one company but filled by another company, FDA permits the use of a small ownership or possession sticker in addition to the drug product label (see Figure B-1).

- Official product name (for single-component gases);
- Statement of ingredients (for gas mixtures);
- Lot number; and
- Net contents, in appropriate units of measure as follows:

- If the medical gas is in a gaseous state in a high pressure final use container, it shall be expressed in liters or cubic feet qualified by the statement "at 70 °F and ## psi"
- If the medical gas is in a liquefied compressed gas state in a high pressure final use container it shall be expressed in gaseous liters or by an appropriate net weight statement
- If the medical gas is in a liquefied state in a portable cryogenic final use container it shall be expressed in gaseous liters, liquid liters (if identified as a liquid measure), gallons, or by an appropriate net weight statement
- If the medical gas is in a refrigerated liquid or high pressure tube transport (i.e., non-final use container), labeling for net quantity of contents is not required or
- If the medical gas is in a large non-portable cryogenic storage container or high pressure storage bank (i.e., non-final use container that supplies product via a pipeline), labeling for net quantity of contents is not required.

An expiration date for drugs is required by 21 CFR; however, FDA has indicated that they do not enforce the requirement for medical gases unless it is specified by a firm's standard operating procedures (SOP) [9]. If specified by the firm's SOP, FDA requires that appropriate stability test data to support the expiration date be maintained.

NOTE—The lot number, net contents, and/or expiration date (if used) can appear on a separate sticker instead of on the main product label. Figure B-2 provides an example of a separate sticker containing supplementary information.

The small ownership sticker shall only identify the cylinder owner (name, address, and/or phone number) and shall contain the words "property of" or "owned by". The sticker shall be placed so it cannot be confused with the product label. The sticker should not contain language that can be confused with language on the product label.

If a separate sticker is used for this information, it shall be applied in close proximity to the main product label.

Property of
ABC Homecare
123 Home Street
Anytown, USA
123-456-7890

Figure B-1—Example of a small ownership sticker

xxxxxxxxx
LOT NO.

xxxx LITERS

EXP DATE
xx/xx/xxxx

Figure B-2—Example of a separate sticker containing supplementary information

B.3 Specific required statements

The following FDA-required statements should be used in conjunction with other applicable labeling and marking information contained in this publication, specifically, Appendix A and applicable illustrative labels in Section 9 for pure gases.

B.3.1 Gaseous and Liquid Oxygen

USP

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.

Produced by Air Liquefaction ¹

¹ Labels shall indicate if the oxygen was produced by the air liquefaction process. Oxygen produced by the air liquefaction process is exempt from the requirements for the USP tests for carbon monoxide and carbon dioxide.

NOTE—Individual states may have state-specific labeling requirements; for example, one state requires the following additional statements on oxygen labels:

- Keep out of reach of children; and
- 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* [16].

NOTE—If medical oxygen is provided as a cryogenic liquid in a cryogenic final use container, e.g., liquid oxygen home unit, that is classified as a medical device, the warning statements above are not required provided the device label of the container provides adequate directions for use in accordance with the device approval and contains the phrase "Rx only."

B.3.2 Carbon Dioxide, Helium, Nitrous Oxide

USP

Rx only

WARNING: Administration of (name of gas) 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 (name of gas) 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.

B.3.3 Gaseous and Liquid Nitrogen**NF****Rx only**

WARNING: Administration of Nitrogen 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 Nitrogen 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.

NOTE—Open-topped dewars filled from a liquid nitrogen NF supply do not require drug or device product labeling; however, they should be identified with the word "Nitrogen."

B.3.4 Medical Air**USP**

WARNING: For breathing support when used by properly trained personnel. For medical applications, **Rx only**.

Administration of Medical Air 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 Medical Air 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.

*Mixture of oxygen USP and nitrogen NF.

* The statement "Mixture of oxygen USP and nitrogen NF" is only required for synthetic air mixtures. The medical air impurities tests are not required if the air is a synthetic mixture of oxygen and nitrogen, the oxygen complies to Oxygen, USP and nitrogen complies to Nitrogen, NF, and this statement appears on the label.

B.4 Oxygen/Nitrogen Medical Mixtures other than Medical Air

B.4.1 Oxygen/Nitrogen Medical Mixtures (nonflammable, nonoxidizing) where the oxygen content is less than 19.5%	
<p>_____ % Oxygen, USP ¹</p> <p>_____ % Nitrogen, NF ¹</p> <p style="text-align: center;">Rx only</p>	
<p>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.</p> <p>WARNING: CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION.</p> <p>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 of compatible materials of construction and 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.</p> <p>FIRST AID: IF ACCIDENTLY INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention.</p> <p>DO NOT REMOVE THIS PRODUCT LABEL (or equivalent wording).</p>	<p style="text-align: right;">Codes</p> <p>H280 OSHA-H01</p> <p>P202 P271+P403 CGA-PG05 CGA-PG20+ CGA-PG10 CGA-PG06 CGA-PG02 CGA-PG27</p> <p>CGA-MP01</p> <p>OSHA-PG01</p>

¹ The USP or NF designation may be placed before or after the component or percentage entry. As an alternate method of stating that the mixture was prepared using USP or NF gases when applicable, the USP or NF designation after each component may be eliminated, and the statement "Gases used to prepare this mixture meet USP or NF specifications where applicable" or equivalent wording may be added to the label. Component names may appear in any order.

NOTE—If this mixture is to be used as a respiratory challenge mix, the label may indicate "FOR USE WITH RESPIRATORY CHALLENGE DIAGNOSTIC EQUIPMENT IN ACCORDANCE WITH MANUFACTURERS INSTRUCTIONS".

Required symbols	
GHS pictogram(s)	Gas cylinder
Transportation label(s)	2.2 Nonflammable Gas
NOTE—Where a pictogram (i.e., DOT label) required under 49 CFR 172.400 appears on a shipped container, the pictogram specified in C.4 of OSHA's Hazard Communication Standard for the same hazard shall not appear [3, 2].	

B.4.2 Oxygen/Nitrogen Medical Mixtures (nonflammable, oxidizing) where the oxygen content is greater than 23.5%		
<p>_____ % Oxygen, USP¹</p> <p>_____ % Nitrogen, NF¹</p> <p style="text-align: center;">Rx only</p>		
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.	Codes
DANGER:	MAY CAUSE OR INTENSIFY FIRE; OXIDIZER. CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED.	H270 H280
	Do not handle until all safety precautions have been read and understood.	P202
	Keep and store away from clothing and other combustible materials.	P220
	Keep valves and fittings free from grease and oil.	P244
	Use and store only outdoors or in a well-ventilated place.	P271+P403
	Use a back flow preventive device in the piping.	CGA-PG05
	Use only with equipment of compatible materials of construction and rated for cylinder pressure.	CGA-PG20+
	Use only with equipment cleaned for oxygen service.	CGA-PG10
	Open valve slowly.	CGA-PG22
	Close valve after each use and when empty.	CGA-PG21
	Protect from sunlight when ambient temperature exceeds 52 °C (125 °F).	CGA-PG06
	Read and follow the Safety Data Sheet (SDS) before use.	CGA-PG02 CGA-PG27
	DO NOT REMOVE THIS PRODUCT LABEL (or equivalent wording).	OSHA-PG01

¹ The USP or NF designation may be placed before or after the component or percentage entry. As an alternate method of stating that the mixture was prepared using USP or NF gases when applicable, the USP or NF designation after each component may be eliminated, and the statement "Gases used to prepare this mixture meet USP or NF specifications where applicable" or equivalent wording may be added to the label. Component names may appear in any order.

Required symbols	
GHS pictogram(s)	Gas cylinder, Flame over Circle
Transportation label(s)	2.2 Nonflammable Gas, 5.1 Oxidizer
NOTE—Where a pictogram (i.e., DOT label) required under 49 CFR 172.400 appears on a shipped container, the pictogram specified in C.4 of OSHA's Hazard Communication Standard for the same hazard shall not appear [3, 2].	

B.5 Oxygen/Helium Medical Mixtures

B.5.1 Oxygen/Helium Medical Mixtures (nonflammable, nonoxidizing) where the oxygen concentration is less than or equal to 23.5%		
<p>_____ % Oxygen, USP ¹</p> <p>_____ % Helium, USP ¹</p> <p style="text-align: center;">Rx only</p>		
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.	Codes
DANGER:	CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. *MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION.	H280 OSHA-H01
	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 of compatible materials of construction and 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.	P202 P271+P403 CGA-PG05 CGA-PG20+ CGA-PG10 CGA-PG06 CGA-PG02 CGA-PG27
FIRST AID:	IF ACCIDENTLY INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention.	CGA-MP01
	DO NOT REMOVE THIS PRODUCT LABEL (or equivalent wording).	OSHA-PG01

¹ The USP or NF designation may be placed before or after the component or percentage entry. As an alternate method of stating that the mixture was prepared using USP or NF gases when applicable, the USP or NF designation after each component may be eliminated, and the statement "Gases used to prepare this mixture meet USP or NF specifications where applicable" or equivalent wording may be added to the label. Component names may appear in any order.

* If the mixture contains concentrations of oxygen from 19.5% up to 23.5%, this statement is not allowed to be on the label.

Required symbols	
GHS pictogram(s)	Gas cylinder
Transportation label(s)	2.2 Nonflammable Gas
NOTE—Where a pictogram (i.e., DOT label) required under 49 CFR 172.400 appears on a shipped container, the pictogram specified in C.4 of OSHA's Hazard Communication Standard for the same hazard shall not appear [3, 2].	