

BELIZE:

**STANDARDS (BELIZE STANDARDS SPECIFICATION FOR
MARKING AND LABELLING OF MEDICAL GAS CYLINDERS)
(DECLARATION AS A COMPULSORY STANDARD)
ORDER, 2023**

ARRANGEMENT OF PARAGRAPHS

1. Citation.
2. Declaration of Compulsory Standard.
3. Purpose of Compulsory Standard.
4. Commencement.

SCHEDULE.

BELIZE:**STATUTORY INSTRUMENT****No. 109 2023**

ORDER made by the Minister of responsible for the Bureau of Standards, on the recommendation of the Belize Bureau of Standards, in exercise of powers conferred upon him by section 9(2) of the Standards Act, Chapter 295 of the Substantive Laws of Belize, Revised Edition 2020, and all other powers thereunto him enabling.

(Gazetted 14th October, 2023).

WHEREAS, section 9(3) of the Standards Act, Chapter 295 of the Laws of Belize provides that the Minister shall, by publication in the *Gazette*, give at least thirty days' notice of his intention to make an Order declaring a compulsory standard and shall thereby indicate the date on which it is intended that the compulsory standard shall come into force;

AND WHEREAS, a notice of intention to declare the BELIZE SPECIFICATION FOR MARKETING AND LABELLING OF MEDICAL GAS CYLINDERS (BZS 1: Part 8: 2023) to be a compulsory standard was published in the Belize *Gazette* dated 19th August 2023;

AND WHEREAS, no objections have been received to the making of the said Order;

NOW, THEREFORE, IT IS ORDERED as follows:–

1. This Order may be cited as the

Citation.

**STANDARDS (BELIZE STANDARDS
SPECIFICATION FOR MARKING AND
LABELLING OF MEDICAL GAS CYLINDERS)
(DECLARATION AS A COMPULSORY STANDARD)
ORDER, 2023.**

Declaration of
Compulsory
standard.
Schedule.

2. The Belize Standard (BZS 1: Part 8: 2023 SPECIFICATION FOR MARKING AND LABELING OF MEDICAL GAS CYLINDERS), the full text of which appears in the Schedule hereto, is hereby declared to be a compulsory standard.

Purpose of
Compulsory
Standard.

3. The standard referred to in paragraph 2 is intended primarily–

- (a) to protect the consumer or user against danger to health or safety;
- (b) to ensure quality in goods produced for home use or for export;
- (c) to prevent fraud or deception arising from misleading advertising or labelling; and
- (d) to require adequate information to be given to the consumer or user.

Commencement.

4. This Order shall come into effect on the **15th day of October 2023.**

SCHEDULE*[paragraph 2]***BELIZE STANDARD
SPECIFICATION FOR MARKING AND LABELLING OF
MEDICAL GAS CYLINDERS**

0 FOREWORD

- 0.1 The medical compressed gas industry has developed precautionary labels and markings for use on containers of compressed gases, cryogenic liquids, and other hazardous materials for the purpose of identifying the contents, warning of principal physical, health, and environmental hazards, and providing appropriate precautionary information following the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
- 0.2 This standard was established to meet the specific labeling and marking needs and methods of preparing label information established by GHS specifically for medical compressed gases in Belize.
- 0.3 Labelling of medical gases in Belize follows the United Nations (UN) regulations established in the GHS.
- 0.4 In drafting this standard, considerable assistance was derived from the following document(s):
- a) CGA C-7-2020 - 11th Edition - Guide to Classification and Labeling of Compressed Gases, Compressed Gas Association, USA.
 - b) Title 49 (Transportation) Parts 100-180, Code of Federal Regulations, U.S. Government Printing Office.

- c) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), United Nations Economic Commission for Europe.

1 SCOPE

- 1.1 This standard provides minimum requirements for labels and markings on compressed gas in cylinders and cryogenic liquid containers cylinders containing for medical gases namely for medical air, oxygen, carbon dioxide, helium, nitrogen, nitrous oxide and mixtures.
- 1.2 Labels shall be applied to compressed gas and cryogenic liquid containers to identify the container contents and to warn of principal physical and health hazards associated with the container and its contents.
- 1.3 Labels as given herein with regard to cylinder handling and storage information may be modified with respect to format so they can be applied as required to fixed storage vessels, portable tanks, tube trailers, cargo tanks, or other packaging.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BZS 28: 2023 Belize Standard Specification for Medical Gases namely for medical air, oxygen, carbon dioxide, helium, nitrogen, nitrous oxide and mixtures.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following terms and definitions shall apply:

- 3.1 **Acute toxicity estimate (ATE)** means the numerical

value that is used to evaluate acute toxicity.

NOTE: For an ingredient, the ATE is derived from the lethal concentration (LC50), if available, or a converted acute toxicity point estimate that is based on an experimentally obtained range or the classification category. For a gas mixture, the ATE is calculated for inhalation toxicity based on the ATE values for all relevant ingredients and the percentage concentration in the product.

3.2 **Adequate ventilation** means the condition falling within any or all of the following categories:

a) Ventilation to reduce levels of the air contaminant below that which may cause personal injury or illness.

NOTE: Values have been established by many sources for specific chemicals such as permissible exposure limits, threshold limit values, and short-term exposure limits.

b) Ventilation sufficient to prevent accumulation to a concentration of contaminant vapor in air at a level in excess of 25% of the level set for the lower flammable limit; or

c) Ventilation sufficient to prevent oxygen-deficient (less than 19.5%) or oxygen-enriched (greater than 23.5%) atmospheres.

3.3 **Corrosive liquid or gas** means liquid or gas when in contact with living tissue causes full thickness destruction of the human skin within a specified period of time.

NOTE: In this publication, this term shall not refer to action on metal surfaces.

3.4 **Critical temperature** means temperature above which a pure gas cannot be liquefied, regardless of the degree of

compression.

- 3.5 **Cryogenic liquid** means refrigerated liquefied gas having a boiling point colder than $-90\text{ }^{\circ}\text{C}$ ($-130\text{ }^{\circ}\text{F}$) at 101.3 kPa, abs (14.7 psia).
- 3.6 **Distributor** means 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.
- 3.7 **Flammable gas** means gas having a flammable range with air at $20\text{ }^{\circ}\text{C}$ ($68\text{ }^{\circ}\text{F}$) and a standard pressure of 101.3 kPa and is classified in one of the two categories:
- Category 1 Gases, which at $20\text{ }^{\circ}\text{C}$ ($68\text{ }^{\circ}\text{F}$) and a standard pressure of 101.3 kPa (14.7 psia): are ignitable when in a mixture of 13% or less by volume in air; or have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit; or
 - Category 2 Gases, other than those of Category 1, which, at $20\text{ }^{\circ}\text{C}$ ($68\text{ }^{\circ}\text{F}$) and a standard pressure of 101.3 kPa (14.7 psia), have a flammable range while mixed in air.
- 3.8 **Flammable liquid** means a liquid having a flash point of not more than $93\text{ }^{\circ}\text{C}$ ($199.4\text{ }^{\circ}\text{F}$) and is classified in one of four categories:
- Category 1 - Flash point $< 23\text{ }^{\circ}\text{C}$ ($73.4\text{ }^{\circ}\text{F}$) and initial boiling point $\leq 35\text{ }^{\circ}\text{C}$ ($95\text{ }^{\circ}\text{F}$);
 - Category 2 - Flash point $< 23\text{ }^{\circ}\text{C}$ ($73.4\text{ }^{\circ}\text{F}$) and initial boiling point $> 35\text{ }^{\circ}\text{C}$ ($95\text{ }^{\circ}\text{F}$);
 - Category 3 - Flash point $\geq 23\text{ }^{\circ}\text{C}$ ($73.4\text{ }^{\circ}\text{F}$) and $\leq 60\text{ }^{\circ}\text{C}$; or
 - Category 4 - Flash point $> 60\text{ }^{\circ}\text{C}$ ($140\text{ }^{\circ}\text{F}$) and $\leq 93\text{ }^{\circ}\text{C}$ ($199.4\text{ }^{\circ}\text{F}$).

- 3.9 **Flash point** means minimum temperature at which a substance gives off flammable vapors that when in contact with sparks or flame ignites.
- 3.10 **Gas** means a normally formless fluid that occupies the space of enclosure and can be changed to the liquid or solid state by the effect of increased pressure, decreased temperature, or both. A gas diffuses:
- 3.10.1 Gases under pressure: gases are classified, according to their physical state when packaged, in one of four groups.
 - 3.10.2 Compressed gas (non-liquefied compressed gas): gas which when packaged under pressure is entirely gaseous at $-50\text{ }^{\circ}\text{C}$ ($-58\text{ }^{\circ}\text{F}$); including all gases with a critical temperature less than or equal to $-50\text{ }^{\circ}\text{C}$ ($-58\text{ }^{\circ}\text{F}$).
 - 3.10.3 Liquefied gas (liquefied compressed gas): gas when packaged under pressure, is partially liquid at temperatures above $-50\text{ }^{\circ}\text{C}$ ($-58\text{ }^{\circ}\text{F}$). A distinction is made between:
 - a) High pressure liquefied gas: a gas with a critical temperature between $-50\text{ }^{\circ}\text{C}$ ($-58\text{ }^{\circ}\text{F}$) and $65\text{ }^{\circ}\text{C}$ ($149\text{ }^{\circ}\text{F}$); and
 - b) Low pressure liquefied gas: a gas with a critical temperature above $65\text{ }^{\circ}\text{C}$ ($149\text{ }^{\circ}\text{F}$).
 - 3.10.4 Refrigerated liquefied gas: gas when packaged is made partially liquid because of its low temperature.
- 3.11 **Health hazard** means chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard.

NOTE: The criteria for determining whether a chemical is classified as a health hazard are detailed in Annex A to §1910.1200—Health Hazard Criteria.

- 3.12 **Irritation** means result of a chemical, either liquid or gas (not a corrosive chemical), that causes a reversible inflammatory effect on living tissue at the site of contact (such as eyes, skin, or respiratory tract).
- 3.13 **High pressure gas** means liquefied or compressed gas in a container that has a pressure of 3450 kPa (500 psi) or higher at 21.1 °C (70 °F).
- 3.14 **Label** means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.
- 3.15 **LC₅₀** means concentration of a substance in air, exposure to which for a specified length of time is expected to cause the death of 50% of the entire defined experimental animal population.

NOTE: LC₅₀ is usually measured as ppm (mol/mol).

- 3.16 **Liquid** means substance or mixture which at 50 °C (122 °F) has a vapor pressure of not more than 300 kPa (44 psi), which is not completely gaseous at 20 °C (68 °F) and at a standard pressure of 101.3 kPa (14.7 psi), and which has a melting point or initial melting point of 20 °C (68 °F) or less at a standard pressure of 101.3 kPa (14.7 psi).
- 3.17 **Manufacturer** means any person or firm who produces, fills, repackages (transfills), or relabels medical drug gas cylinders.

- 3.18 **Mixture** means mixture, or a solution composed of two or more substances in which they do not react.
- 3.19 **Oxidizing gas** means any gas that can, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE: Pure gases or mixtures with an oxidizing potential greater than 23.5% oxygen in nitrogen by volume as defined in ISO 10156:2010 or an equivalent testing method are regarded as oxidizing for DOT, TC, and the United States Occupational Safety and Health Administration (OSHA) regulatory purposes.

- 3.20 **Respiratory Quotient (RQ)**, also known as respiratory ratio, means the volume of carbon dioxide released over the volume of oxygen absorbed during respiration.

4 REQUIREMENTS

4.1 General Requirements

- a) All statements on labels shall be brief, accurate, and expressed in simple, easily understood terms.
- b) Precautionary information shall be used only as appropriate. Excessive information should not be used. Unnecessary wording on labels could develop a disregard for the labels and markings. It is desirable to use uniform precautionary wording when indicating the same hazards for different gases.
- c) Precautionary statements shall be in legible type that is in contrast by typography or layout with other printed matter on the labels and markings. The label shall be displayed in a conspicuous place on the container so it can easily be read by the handler or

user.

- d) Any additional information regarding hazards, precautionary information, response, and storage and disposal should appear in the appropriate section of a product's Safety Data Sheet (SDS). The information on the label shall be consistent with the SDS, and the label shall reference the product's SDS.
- e) Gas mixtures can have properties that are similar to those of the individual components. Labels for mixtures shall be based on the physical and health hazards of the finished mixture, based on the physical and health hazards of its ingredients in accordance with the criteria given in Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- f) All United States Department of Transportation (DOT-4L/TC-4LM) liquid cylinders shall have additional product identification visible from all directions. Refer to Annex F for additional instructions.

4.2 Specific Requirements

4.2.1 Label content for hazard communication

Information required on labels is as follows:

a) Product Identifier;

Product identifier shall be the proper shipping name and shall match the name used on the SDS. It provides a unique means by which the user can identify the gas.

b) Signal Word;

The signal word shall indicate the relative

degree of severity of a hazard in the diminishing order of DANGER or WARNING. When a product has more than one hazard, only the signal word corresponding to the class of the greatest immediate hazard shall be used. The assignment of signal words is based upon the hazard classification. DANGER is mostly used for the more severe hazard categories, while WARNING is mostly used for the less severe.

c) Symbol(s)/Pictogram(s);

Applicable GHS pictograms shall be affixed to indicate hazards in the workplace. The GHS pictogram shall be no less than 10 mm (0.39 in) on each side inclusive of the red border and oriented as a diamond.

Mixture means mixture, or a solution composed of two or more substances in which they do not react.

3.19 **Oxidizing gas** means any gas that can, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE: Pure gases or mixtures with an oxidizing potential greater than 23.5% oxygen in nitrogen by volume as defined in ISO 10156:2010 or an equivalent testing method are regarded as oxidizing for DOT, TC, and the United States Occupational Safety and Health Administration (OSHA) regulatory purposes.

3.20 **Respiratory Quotient (RQ)**, also known as respiratory ratio, means the volume of carbon dioxide released over the volume of oxygen absorbed during respiration.

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- a) All statements on labels shall be brief, accurate, and expressed in simple, easily understood terms.
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- c) Precautionary statements shall be in legible type that is in contrast by typography or layout with other printed matter on the labels and markings. The label shall be displayed in a conspicuous place on the container so it can easily be read by the handler or user.
- d) Any additional information regarding hazards, precautionary information, response, and storage and disposal should appear in the appropriate section of a product's Safety Data Sheet (SDS). The information on the label shall be consistent with the SDS, and the label shall reference the product's SDS.
- e) Gas mixtures can have properties that are similar to those of the individual components. Labels for mixtures shall be based on the physical and health hazards of the finished mixture, based on the physical and health hazards of its ingredients in accordance with the criteria given in Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- f) All United States Department of Transportation (DOT-4L/TC-4LM) liquid cylinders shall have additional product identification visible from all

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4.2 Specific Requirements

4.2.1 Label content for hazard communication

Information required on labels is as follows:

a) **Product Identifier;**

Product identifier shall be the proper shipping name and shall match the name used on the SDS. It provides a unique means by which the user can identify the gas.

b) **Signal Word;**

The signal word shall indicate the relative degree of severity of a hazard in the diminishing order of DANGER or WARNING. When a product has more than one hazard, only the signal word corresponding to the class of the greatest immediate hazard shall be used. The assignment of signal words is based upon the hazard classification. DANGER is mostly used for the more severe hazard categories, while WARNING is mostly used for the less severe.

c) **Symbol(s)/Pictogram(s);**

Applicable GHS pictograms shall be affixed to indicate hazards in the workplace. The GHS pictogram shall be no less than 10 mm (0.39 in) on each side inclusive of the red border and oriented as a diamond.



Figure 1: Cryogenic liquid label

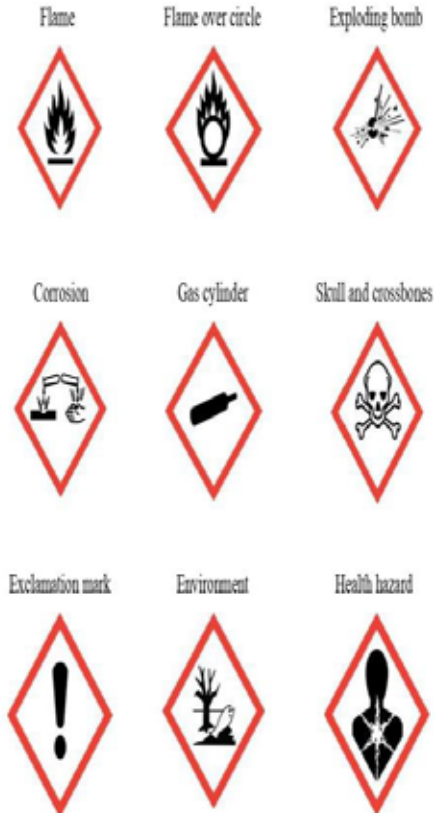


Figure 2: GHS Pictograms



In addition, the background color on the NON-FLAMMABLE GAS label must be green.

d) Hazard Statement(s):

A hazard statement (such as FLAMMABLE GAS) gives notice of the hazards present in connection with the customary or reasonably anticipated handling or use of the product and shall follow the signal word. If a product has several hazardous properties, a statement of each significant hazard shall be included. Examples of hazard statements and associated signal words are shown in Table 1.

Table 1: Examples of hazard statements and their associated signal words

Hazard statement	Associated signal word
EXTREMELY FLAMMABLE GAS (H220)	DANGER
MAY FORM EXPLOSIVE MIXTURES WITH AIR (CGA-HG04)	
TOXIC IF INHALED (H331)	
CAUSES SEVERE SKIN BURNS AND EYE DAMAGE (H314)	
MAY CAUSE OR INTENSIFY FIRE; OXIDIZER (H270)	

MAY CAUSE CANCER (H350) CATCHES FIRE SPONTANEOUSLY IF EXPOSED TO AIR (H250)	
CORROSIVE TO THE RESPIRATORY TRACT (CGA- HG22) CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED (H280) HARMFUL IF INHALED (H332) MAY CAUSE DAMAGE TO CENTRAL NERVOUS SYSTEM (H371) MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION (OSHA-HG01)	WARNING

e) Precautionary Statements (prevention, response, storage, and disposal);

Precautionary statements are intended to supplement the hazard statement(s) by briefly describing measures to be taken to avoid injury or damage from stated hazards. Normally, one or more precautionary measures accompany each hazard statement.

f) Response (first aid, emergency response, accidental spillage or exposure)

Instructions in case of contact and exposure shall be included where the results of contact or exposure are severe and immediate treatment is desirable, and where simple remedial measures can be taken safely before medical assistance is available. These instructions shall be limited to recognized

procedures based on simple methods and commonly available materials. Simple remedial measures (such as washing or removing clothing) shall be included where they lessen injury following contact or exposure. Additional instructions in case of fire or leak may be included on the labels or in safety literature referenced on the label. Such references on the label to safety literature could include SDSs, supplier's safety booklets, or Compressed Gases Association (CGA) publications.

g) Storage (handling and storage)

Important instructions for handling and storage (such as "Use and store only outdoors or in a well-ventilated place" and "Close valve after each use and when empty") should be included on the label. Additional instructions for container handling and storage may be included on the labels or in safety literature referenced on the label. Such references on the label to safety literature could include SDSs, supplier's safety booklets, or CGA publications.

- h)** Name, telephone number, and address of the manufacturer, importer, or other responsible party.

4.2.2 Label content for transport

See Annex A for information on DOT/TC requirements.

4.2.3 Label content for medical applications

See Annexes B and C for additional United States Food and Drugs Administration (FDA) requirements.

5 LABEL DIAGRAMS AND EXAMPLES

- 5.1 Label elements and label element codes for pure gases are provided in Annex D and include the required signal word, pictogram(s), and hazard and precautionary statements. The label diagrams as illustrated in Figures 5 and 6 provide examples of how label elements may be arranged on a shoulder and sidewall label for compressed gas cylinders or cryogenic liquid containers.
- 5.2 Examples of gas-specific labels prepared per the label diagrams and in accordance with the general principles given in this publication and showing the minimum requirements are illustrated in Figures below.
- 5.3 The example labels might not contain all language necessary to comply with government regulations. It is the responsibility of the gas supplier to ensure that the label contains any additional information necessary to comply with applicable government regulations.
- 5.4 The example labels show minimum warnings based upon sources, technical information, and experience at the time this edition was published. They are subject to periodic review and might change as new information becomes available.
- 5.5 CGA has developed additional hazard and precautionary statements to convey further information specific to the industrial and medical compressed gas industry. These additional CGA hazard and precautionary statements are included on the label examples as applicable and can be found in Annexes E and G. The rules for the use of CGA hazard and precautionary statements on labels also appear in Annex E.
- 5.6 If a label has a transport pictogram, and a health pictogram, GHS pictogram may be used.

Table 2: Key for Figures 5 and 6

Color block	Figure area
1	Proper shipping name (PSN). Minimum type size 5 mm (0.1875 in).
2	United States Pharmacopeia (USP)/ National Formulary from the United States (NF) designation, if permitted.
3	Components for N.O.S. mixtures. At least two components listed within parentheses, percentages may be included.
4	UN number. Minimum type size 6 mm (0.2 in) for cylinders with a water capacity of 60 L or less, 12 mm (0.47 in) for cylinders with a water capacity greater than 60 L.
5	RQ or INHALATION HAZARD, if required. Minimum type size 2 mm (0.0625 in).
6	Transportation diamond, square-on-point. Minimum size 30 mm (1.25 in).
7	FDA-required signal word, if necessary.
8	FDA-required phrases, if necessary.
9	OSHA-required signal word.
10	OSHA-required hazard statement.
11	OSHA-required precautionary statements, additional language if necessary.
12	Name, address, and phone number of responsible party.
13	OSHA-required pictogram, if necessary. Minimum size 10 mm (0.39in).



Figure 1: Example of a cylinder shoulder label layout

This example label is provided for illustrative purposes only. See Annex A for specifics regarding the height of the PSN, transportation diamond, UN number, and RQ/INHALATION HAZARD warnings.



Figure 4: Example of an Air, Compressed cylinder shoulder label



Figure 5: Example of an Oxygen cylinder shoulder label for transport and use

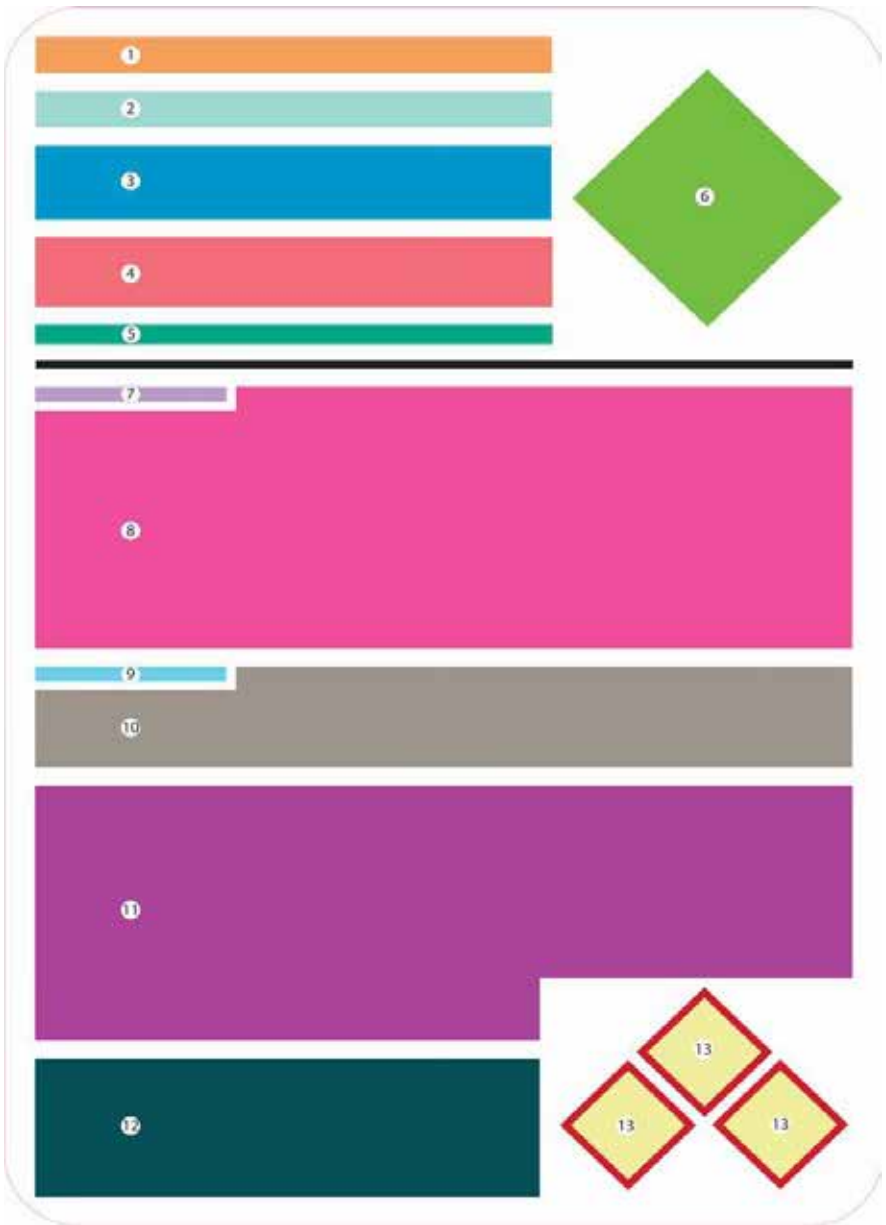


Figure 2: Example of a cylinder sidewall label layout

This example label is provided for illustrative purposes only. See Appendix A for specifics regarding the height of the PSN, transportation diamond, UN number, and RQ/INHALATION HAZARD warnings.

**CARBON DIOXIDE,
REFRIGERATED LIQUID
UN2187**



WARNING: CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY
MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION
MAY INCREASE RESPIRATION AND HEART RATE

Do not handle until all safety precautions have been read and understood.
Use and store only outdoors or in a well-ventilated place.
Wear cold insulating gloves, face shield, and eye protection.
Use a back flow preventive device in the piping.
Use only with equipment of compatible materials of construction and rated for cylinder pressure.
DO NOT change or force fit connections.
Do not open valve until connected to equipment prepared for use.
Close valve after each use and when empty.
Never put cylinders in unventilated areas of passenger vehicles.
Always keep container in upright position.
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.

IF ON SKIN: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.

DO NOT REMOVE THIS PRODUCT LABEL.

COMPANY NAME
COMPANY ADDRESS
COMPANY PHONE NUMBER

Figure 3: Example of a Carbon Dioxide, Refrigerated Liquid cylinder sidewall label

This example label is provided for illustrative purposes only. See Appendix A for specifics regarding the height of the PSN, transportation diamond, UN number, and RQ/INHALATION HAZARD warnings.

Annex A
CGA marking system for compressed gas cylinders
(Normative)

A.1 Labels and Markings

- A.1.1 The basic marking, illustrated in Figure A-1, shall consist of a diamond-shaped figure indicating the hazard class of the contained gas combined with a panel containing the proper shipping name of the contained gas and the UN identification number. The panel shall be located to the left of the diamond.
- A.1.2 The word GAS may be used with the hazard identification words FLAMMABLE or NON-FLAMMABLE on the diamond-shape figure. The hazard class text may be displayed on one or two lines.
- A.1.3 Certain gases with subsidiary hazards require multiple square-on-point (diamond) labels. For such gases, the basic marking shall include additional diamonds denoting the subsidiary hazard or hazards. Hazard class numbers shall appear on both the primary and subsidiary hazard diamond or diamonds. The diamonds shall be adjacent to one another, but their adjoining points are allowed to be overlapped by not more than 10 mm (0.375 in), as illustrated in Figures A-2 and A-3. The primary hazard diamond shall be placed to the left of the subsidiary hazard diamond(s) and not overlapped. Subsidiary labels shall only be overlapped on the left side.
- A.1.4 The letters USP or NF are also allowed to be shown in this panel following the proper shipping name or product identification number. USP refers to United States Pharmacopeia and NF refers to National Formulary, both of which are published by the United States Pharmacopeia. Refer to Annexes B and C for additional information.
- A.1.5 For Medical Air, the proper shipping name is "Air, compressed" and the USP monograph name is "Medical

Air, USP." The letters USP are not allowed to follow the proper shipping name "Air, compressed." "Medical Air, USP" may appear in the left panel along with the proper shipping name as shown in Figure A-5, or it may appear elsewhere on the label.

A.2 Precautionary Information

CGA's marking system, illustrated in Figure A-5, provides for additional information on cylinders such as the name of the supplier, precautions to be observed in the handling, storage, and use of the cylinder and/or its contents, and other information of value to the user. CGA's marking system allows information for medical or industrial use to be included as required by other regulatory bodies. It allows this additional information to appear above, beside, or below the basic marking as long as it does not interfere with the recognition of the basic marking.

A.3 Label Dimensions and Modifications

The diamond figure in the basic marking shall measure at least 30 mm (1.25 in) on each side and the corners shall have an included angle of 90 degrees. The hazard class number should be not less than 5 mm (0.1875 in) in height. The hazard class words (for example: flammable gas) are allowed to be included in the diamond in letters not less than 3.175 mm (0.125 in) in height.

A.4 Left panel

A.4.1 The panel to the left of the diamond shall be white and shall be imprinted with the proper shipping name and the UN identification number of the contained gas in black characters. The characters of the shipping name shall be no less than 5 mm (0.1875 in) in height. The UN identification number shall be:

- a) 12 mm (0.47 in) in height for containers greater than 60 L (132 lb.) water capacity;
- b) No less than 6 mm (0.2 in) in height for containers greater than 5 L (11 lb.) to less than or equal to 60 L

(132 lb.) water capacity; or

- c) Marked in a size appropriate for the package for containers less than or equal to 5 L (11 lb.) water capacity.

A.4.2 The panel shall measure not less than 25 mm (1 in) from top to bottom but is allowed to vary in length to accommodate the proper shipping name.

A.4.3 Where required, the letters RQ and/or the words INHALATION HAZARD shall be printed in letters not less than 2 mm (0.0625 in) in height.

A.5 N.O.S. Mixtures

For gas mixtures classified as N.O.S., the technical names of at least two components that most predominantly contribute to the hazards of the mixture shall appear in parenthesis in association with the proper shipping name. The percentages of the components may be included.

A.6 Additional requirement

A.6.1 The basic marking shall be located (a) when space permits, on the shoulder of the cylinder, but not covering the current test date, requalification date, or any other required permanent markings, or (b) on the side of the cylinder, at a point approximately two thirds of the distance from the cylinder bottom to the top of the valve or cap.

A.6.2 The complete CGA marking system may be of any size or shape suitable for application to the cylinder on which it is to be used, subject to the restrictions that the basic marking shall occupy a position of prominence and that the marking system elements meet minimum size requirements.

A.6.3 The complete CGA marking system may have as a background color any color that suits the user with the

exception that the panel to the left of the diamond shall be white and there shall be a contrast between the background color and the color that is required for the diamond in the basic marking. When an identical or similar background color is desirable, this contrast may be accomplished by providing a border of contrasting color to separate the basic marking from the background. A similar border is required where the basic marking is to be applied to a non-contrasting surface.

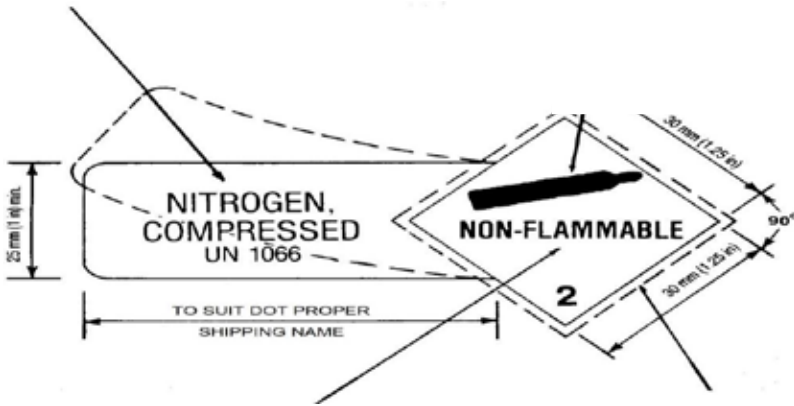
- A.6.4 The basic marking system shall be firmly affixed to the container and shall be of materials that are durable under conditions incident to transportation, storage, and use and shall be maintained in legible condition.
- A.6.5 The basic marking and/or CGA's marking system shall remain affixed to the cylinder, full or empty, as long as it remains in the same gas service. The basic marking provides identification of the hazardous material contained in a filled cylinder. The information is of equal value to the handlers of empty cylinders, as it provides identification of any residual hazardous material that could be present in the cylinder. The removal or replacement of the basic marking shall, therefore, be performed only by, or at the direction of, the supplier responsible for filling the cylinder.

A.7 Illustrative examples

These illustrations use the style of hazard labels (square-on-point).

White panel containing the proper shipping name and UN identification number of the gas. The panel may be either curved or rectangular.

Color of the diamond, hazard class number, and pictorial symbol are to be in accordance with comparable GHS labels. The hazard class number shall not be less than 5 mm (0.1875 in) in height. The pictorial symbol shall be proportional in size to that shown in the referenced section.



Hazard class words, in letters not less than 30 mm (1.25 in), may be used.

When necessary to provide distinction between the color of the diamond and any background color, a 2-mm (0.0625-in) border of contrasting color shall be used.

NOTE:

The word GAS may be included in the 30-mm (1.25-in) diamond of the basic marking. The hazard class text may be displayed on one or two lines.

Figure A-1: Basic markings (not to scale)

The basic marking in Figures A-2 and A-3 illustrate an example when an additional diamond is added to denote the subsidiary hazard. The primary hazard diamond overlaps the subsidiary hazard.

The colors of the individual diamonds shall be in accordance with GHS regulations. The primary hazard diamond shall be placed to the left of the subsidiary hazard diamond(s).

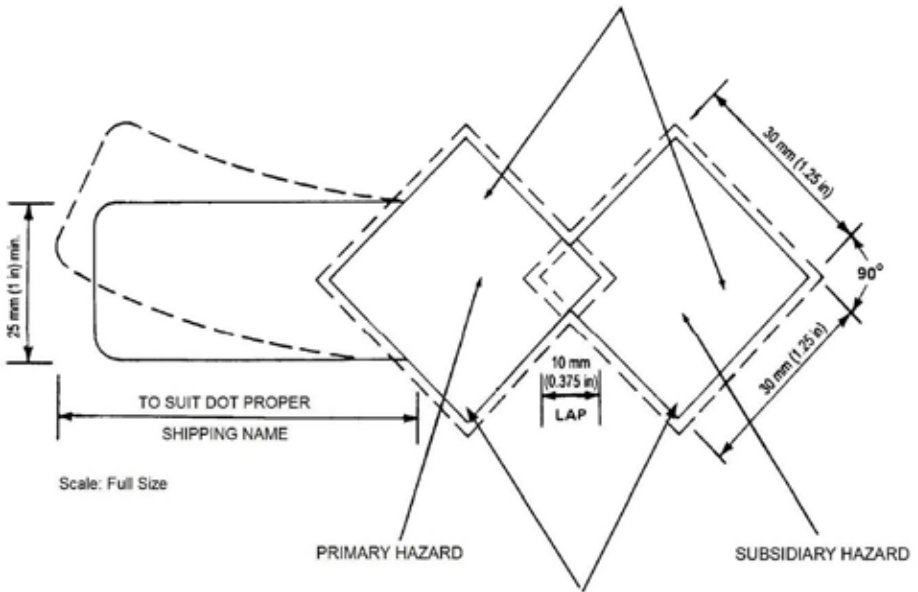
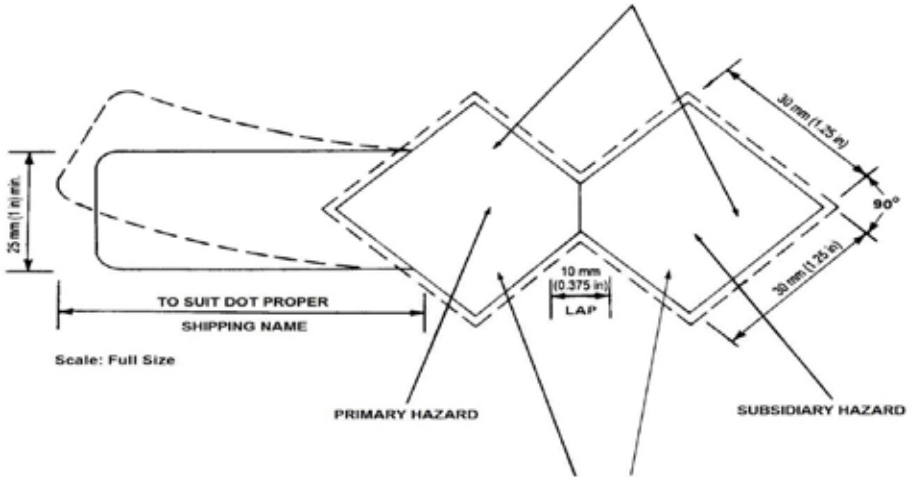


Figure A-2: Basic markings for multiple hazard diamonds (overlapped)

The primary and subsidiary hazard diamonds are truncated with the primary hazard diamond always on the left.

The colors of the individual diamonds shall be in accordance with GHS. The primary hazard diamond shall be placed to the left of the subsidiary hazard diamond(s).



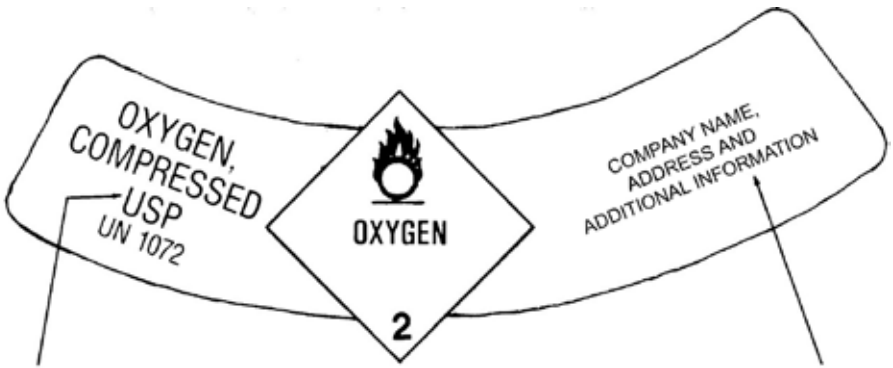
NOTE: For shipments within the United States or to Canada that originate in the United States, truncating of the diamonds is permitted.

NOTE: When required by FDA, 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-3: Basic markings for multiple hazard diamonds (truncated)



Figure A-4: Example of CGA marking system (not to scale)



When the USP/NF markings are required by FDA, 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.

Figure A-5: Example of CGA marking system for domestic shipment of oxygen (not to scale).

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

This guide contains what is considered to be the minimum requirements for medical gas labels.

This Annex should be used in conjunction with other applicable labeling and marking information contained in this publication. For designated medical gases (oxygen, nitrogen, medical air, nitrous oxide, carbon dioxide, and helium), use Annex A and the example labels shown in this Annex.

For medical drug gas mixtures, use Annexes E and G.

The phrases presented as hazard and precautionary statements (i.e., not the Warning statement that begins with “Administration of ...”) are directed to the persons who are handling or administering the gas and not the person to whom the gas may ultimately be administered. In some cases when the first aid statement "If Inhaled" is indicated by Annex G, it is appropriate to modify those words to "If Accidentally Inhaled" given that drug gases and gas mixtures are purposely intended to be inhaled by the person to whom they are administered.

B.1 General requirements

All medical drug gas labels shall bear the:

B.1.1 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:

- a) “Manufactured for (name)”
- b) “Distributed by (name)”
- c) “Manufactured by (name) for (name)”
- d) “Manufactured for (name) by (name)”
- e) “Distributor: (name)” or
- f) “Marketed by (name)”;

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

- g) Official product name (for single-component gases);
- h) Statement of ingredients (for gas mixtures including %);
- i) Lot number; and
- j) Net contents, in appropriate units of measure as follows:
 - i. 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"
 - ii. 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
 - iii. 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
 - iv. 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
 - v. 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.

B.1.2 Expiration date is not a mandatory requirement for medical gases. If manufacturer's Standard Operating Procedures (SOP) requires that appropriate stability test

data to support the expiration date, it may appear with other information on a separate sticker instead of the main product label or in the Purity Certificate.

NOTE: The lot number and/or net contents may 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.

B.1.3 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.

B.1.4 If a separate sticker is used for this information, it shall be applied in close proximity to the main product label.

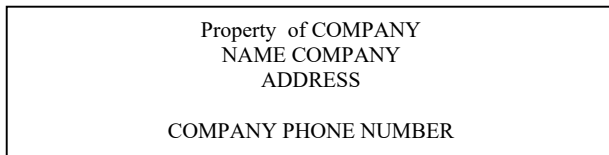
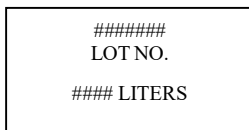


Figure B-1: Example of a small ownership sticker



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."

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

B.2 Specific required statements for certain Designated Medical Gases

The following example labels include required statements used in conjunction with other applicable labeling and marking information contained in this publication. Statements are appropriate for both compressed and cryogenic liquid labels for Designated Medical Gases

Example of an Oxygen, Compressed USP cylinder label text.

- a) OXYGEN, COMPRESSED
- b) USP
- c) UN 1072
- d) WARNING:
 - i. For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications. By prescription only.
 - ii. 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.
- e) Produced by Air Liquefaction
- f) Keep out of reach of children; and
- g) This container is to be refilled with oxygen USP only by establishments registered as a drug manufacturer or transfiller.
- h) DANGER:
 - i. MAY CAUSE OR INTENSIFY FIRE.
 - ii. OXIDIZER.
 - iii. CONTAINS GAS UNDER PRESSURE. MAY EXPLODE IF HEATED.
- i) Do not handle until all safety precautions have been read and understood.
- j) Keep and store away from clothing and other combustible materials.

- k) Keep valves and fittings free from grease and oil.
- l) Use and store only outdoors or in a well-ventilated place.
- m) In case of fire: stop leak if safe to do so.
- n) Use back flow preventive device in the piping.
- o) Use only with equipment of compatible materials of construction and rated for cylinder pressure.
- p) Use only equipment cleaned for oxygen service.
- q) Do not open valve until connected to equipment prepared for use.
- r) Open valve slowly.
- s) Close valve after each use and when empty.
- t) Protect from sunlight when ambient temperature exceeds 52°C (125.6 °F)
- u) Read and follow the Safety Data Sheet (SDS) before use.
- v) DO NOT REMOVE THIS LABEL.
- w) COMPANY NAME, ADDRESS AND PHONE NUMBER.

NOTE: Consideration should be given to adding a statement on medical oxygen cylinders that reads "Do not smoke" to advise consumers.

This example label is provided for illustrative purposes only. See Annex A for specifics regarding height of proper shipping name, transportation diamond, UN number, and RQ/INHALATION HAZARD warnings.

Example of an Oxygen, Refrigerated Liquid USP cylinder label text

- a) OXYGEN, REFRIGERATED LIQUID
- b) USP
- c) UN 1073
- d) WARNING:
 - i. For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications. By prescription only.
 - ii. 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.

- e) Produced by Air Liquefaction
- f) Keep out of reach of children; and
- g) This container is to be refilled with oxygen USP only by establishments registered as a drug manufacturer or transfiler.
- h) DANGER:
 - i. MAY CAUSE OR INTENSIFY FIRE.
 - ii. OXIDIZER.
 - iii. CONTAINS REFRIGERATED GAS. MAY CAUSE CRIOGENIC BURNS OR INJURY.
 - iv. COMBUSTIBLES IN CONTACT WITH OXIDIZING REFRIGERATED LIQUIDS MAY EXPLODE ON IGNITION OR IMPACT.
- i) Do not handle until all safety precautions have been read and understood.
- j) Keep and store away from clothing and other combustible materials.
- k) Keep valves and fittings free from grease and oil.
- l) Use and store only outdoors or in a well-ventilated place.
- m) Wear cold insulating gloves, face shields and eyes protection.
- n) In case of fire: stop leak if safe to do so.
- o) Use back flow preventive device in the piping.
- p) Use only with equipment of compatible materials of construction and rated for cylinder pressure.
- q) Use only equipment cleaned for oxygen service.
- r) DO NOT change or force fit connections.

- s) Avoid spills. Do not walk on or roll equipment over spills.
- t) Do not open valve until connected to equipment prepared for use.
- u) Open valve slowly.
- v) Close valve after each use and when empty.
- w) Always keep container in upright position.
- x) Read and follow the Safety Data Sheet (SDS) before use.
- y) **FIRST AID**
 - i. **IF ON SKIN:** Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.
- z) **DO NOT REMOVE THIS LABEL.**
- aa) **COMPANY NAME, ADDRESS AND PHONE NUMBER.**

NOTE: Consideration should be given to adding a statement on medical oxygen cylinders that reads "Do not smoke" to advise consumers.

B.3 Required statements for certain combinations of Designated Medical Gases other than Medical Air

- B.3.1 The following-required statements shall be used in conjunction with other applicable labeling and marking information contained in this publication, specifically Annexes A, E and G.

a) Oxygen/Nitrogen Medical Mixtures

_____ % Oxygen, USP ¹ _____ % Nitrogen, NF ¹ Rx only
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.

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.”

b) Oxygen/Helium Medical Mixtures

_____ % Oxygen, USP ¹ _____ % Helium, USP ¹ Rx Only
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.

¹ 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.

c) Oxygen/Carbon Dioxide Mixtures

_____ _____ _____	% Oxygen, USP ¹ % Carbon Dioxide, USP ¹
T h e s	Rx only
WARNING: a t e m e n	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.

t “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.

d) Oxygen/Carbon Dioxide/Nitrogen Medical Mixture

_____ _____ _____	% Oxygen, USP ¹ % Carbon Dioxide, USP ¹ % Nitrogen, NF ¹
Rx only	
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 pre- cautions to be taken.

¹ “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”.

Annex C

CGA labeling guide for compressed medical gases classified as medical devices or used with medical devices (Normative)

This Annex was revised to be consistent with current industry practices as they apply to the labeling of certain compressed gases classified as medical devices or used with medical devices.

This guide should be used in conjunction with other applicable labeling and marking information contained in this publication, specifically Annexes A and D.

C.1 General requirements

All compressed gas medical device labels shall bear the following information:

- a) Name and address of manufacturer or distributor. Where the medical gas is not manufactured by the person or firm appearing on the label, as is the case with a distributor, the name identified on the label shall be qualified by the phrase:
 - i. “Manufactured for (name)”
 - ii. “Distributed by (name)” or
 - iii. Any other wording that expresses the connection between the person or firm named on the label and the medical device gas;
- b) Proprietary name and established name (common or usual name), if any;
- c) Statement on the application for use;
- d) Lot number;
- e) Statement of ingredients (including % mol/mol);
- f) Adequate directions for use (cylinder handling and storage); and

- g) Net contents, in units of measure as follows:
- i. 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 ##2000 psi”
 - ii. 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
 - iii. If the medical gas is in a liquefied state in a portable cryogenic final use container shall be expressed in gaseous liters, liquid liters (if identified as a liquid measure), gallons, or by an appropriate net weight statement or
 - iv. 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.
- h) The lot number and/or net contents may appear on the main product label or on a separate sticker instead of on the main product label. If a separate sticker is used for this information, it shall be applied in close proximity to the required main product label.
- i) Open-topped dewars filled from a liquid nitrogen NF supply do not require drug or device product labeling but should be identified with the word "Nitrogen."

C.2 Minimum required statements

The following required statements shall be used in conjunction with other applicable labeling and marking information contained in this publication, specifically Appendix A and applicable hazard and precautionary statements (identified by code designations), signal words, and GHS or DOT pictograms provided in Annex D.

C.2.1 Lung Diffusion Mixtures

_____ % mol/mol ¹ carbon monoxide
 _____ % mol/mol (name of gas) USP or NF when applicable ²
 _____ % mol/mol (name of gas) ²
 _____ % mol/mol (name of gas) ²
 _____ % mol/mol (name of gas)

FOR USE WITH LUNG DIFFUSION DIAGNOSTIC EQUIPMENT IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS.
NOT FOR DRUG USE.

WARNING: Administration of lung diffusion mixtures 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 lung diffusion 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.

FIRST AID: **IF ACCIDENTLY INHALED:** Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention.

1 As an alternate method the statement "All concentrations are expressed as % mol/mol" or equivalent wording may be used instead of using % mol/mol after each component. If the mixture does not contain carbon monoxide, the "% mol/mol carbon monoxide" statement shall not appear.

2 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.

C.2.2 Blood Gas Mixtures

_____ % mol/mol ¹ (name of gas)
 _____ % mol/mol (name of gas)
 _____ % mol/mol (name of gas)

FOR CALIBRATION OF BLOOD GAS ANALYZERS IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS.

NOT FOR DRUG USE.

NOT FOR INHALATION.

¹ As an alternate method the statement “All concentrations are expressed as % mol/mol” or equivalent wording may be used instead of using % mol/mol after each component.

C.2.3 Calibration Gas Mixtures

- a) Medical gas calibration gas mixtures can fall into three categories based on the number and concentration of their components:
- nonflammable, nonoxidizing where the oxygen concentration is less than or equal to 23.5%, including mixtures that do not contain oxygen;
 - nonflammable, oxidizing where the oxygen concentration is greater than 23.5%; or
 - flammable.
- b) Because calibration gas mixtures can contain many different components at various concentrations, the label for calibration gas mixtures shall include, in addition to the information shown below, hazard and precautionary statements and appropriate GHS or DOT pictograms and the statements in Annexes D, E and G.

_____ % mol/mol ¹ (name of gas)
_____ % mol/mol (name of gas)
_____ % mol/mol (name of gas)

FOR CALIBRATION OF MEDICAL ANALYZERS IN
ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS.

NOT FOR DRUG USE.

NOT FOR INHALATION.

¹ As an alternate method the statement “All concentrations are expressed as % mol/mol” or equivalent wording may be used instead of using % mol/mol after each component.

C.3.4 Laser Gases and Laser Gas Mixtures (containing components of noble gases, nitrogen, and/or carbon dioxide)

_____ % mol/mol¹ (name of gas)

_____ % mol/mol (name of gas)

_____ % mol/mol (name of gas)

FOR USE WITH MEDICAL LASER EQUIPMENT. USE IN ACCORDANCE WITH THE EQUIPMENT MANUFACTURER'S INSTRUCTIONS.

NOT FOR DRUG USE.

NOT FOR INHALATION.

FOR USE ONLY BY OR UNDER THE SUPERVISION OF A LICENSED PRACTITIONER WHO IS EXPERIENCED IN THE USE OF LASER EQUIPMENT.

¹ As an alternate method the statement "All concentrations are expressed as % mol/mol" or equivalent wording may be used instead of using % mol/mol after each component.

C.3.5 Artificial Atmosphere Gas Mixtures (both aerobic and anaerobic)

- a) Artificial atmosphere gas mixtures can fall into three categories based upon the number and concentration of their components:
 - i. nonflammable, nonoxidizing where the oxygen concentration is less than or equal to 23.5%, including mixtures that do not contain oxygen;
 - ii. nonflammable, oxidizing where the oxygen concentration is greater than 23.5%; or
 - iii. flammable.
- b) Because artificial atmosphere gas mixtures can contain many different components at various concentrations, the label for artificial atmosphere gas mixtures shall include, in addition to the information shown below, hazard and precautionary statements and appropriate GHS or DOT pictograms and the statements in Annexes D, E and G.

_____ % mol/mol ¹ (name of gas)

_____ % mol/mol (name of gas)

_____ % mol/mol (name of gas)

BIOLOGICAL ATMOSPHERE MIXTURE FOR CULTURE
GROWTH. ²

FOR LABORATORY USE ONLY.

NOT FOR DRUG USE.

NOT FOR INHALATION.

¹ As an alternate method the statement “All concentrations are expressed as % mol/mol” or equivalent wording may be used instead of using % mol/mol after each component.

² While commonly used for this application, mixtures could have other applications and therefore this statement may be removed as applicable.

Annex D

Pure product classifications (Normative)

This Annex includes the information necessary to create pure material GHS labels, which includes GHS classifications with corresponding hazard and precautionary statements, hazard categories, signal word, and GHS pictogram(s) or/ DOT for the pure gases listed in this publication.

For ease of reference, the CAS number, if available, is provided. This information is not required for a GHS-compliant label but can be useful for product identification. This Annex does not provide the proper shipping name (PSN) or other information required to develop transportation labels.

See Annexes E and G for wording for the hazard and precautionary statements used in this guideline.

Carbon Dioxide, Refrigerated Liquid	Carbon Dioxide	Air, Compressed	Gas name
124-38-9	124-38-9	132259-10-0	CAS number
Gases underpressure Simple asphyxiant	Gases underpressure Simple asphyxiant	Gases underpressure	Hazard class
RefrigeratedLiquefiedgas	Liquefied gas	Compressedgas	Hazard category
Warning	Warning	Warning	Signal word
Gas cylinder	Gas cylinder	Gas cylinder	GHS pictogram(s)
2.2 Nonflammable Gas	2.2 Nonflammable Gas	2.2 Nonflammable Gas	Transportationlabel
H281	H280	H280	Hazard statements
OSHA-H01	OSHA-H01		OSHA-required hazard statement
CGA-HG03	CGA-HG01 CGA-HG03	CGA-HG24	CGA-required hazard statements
P202 P271+P403 P282	P202P261P262 P271+P403P280	P202	Prec. statements: prevention
P304, P340, P313, P302, P336, P315	P304, P340, P313, P302, P336, P315		Prec. statements: response
			Prec. statements:

			storage
			Prec. statements: disposal
OSHA-PG01	OSHA-PG01	OSHA-PG01	OSHA-required precautionary statement
CGA-PG05 CGA-PG06 CGA-PG11 CGA-PG12 CGA-PG20 CGA-PG23 CGA-PG24 CGA-PG27	CGA-PG02 CGA-PG05 CGA-PG06 CGA-PG11 CGA-PG12 CGA-PG27	CGA-PG02 CGA-PG05 CGA-PG06 CGA-PG10 CGA-PG12 CGA-PG27	CGA-required precautionary statements

Nitrogen	Nitrogen, Refrigerated Liquid	Helium, Refrigerated Liquid	Helium	Gas name
7727-37-9	7727-37-9	7440-59-7	7440-59-7	CAS number
Gases underpressure Simple asphyxiant	Gases underpressure Simple asphyxiant	Gases underpressure Simple asphyxiant	Gases under pressure Simple asphyxiant	Hazard class
Compressed gas	Refrigerated Liquefied gas	Refrigerated Liquefied gas	Compressed gas	Hazard category
Warning	Warning	Warning	Warning	Signal word
Gas cylinder	Gas cylinder	Gas cylinder	Gas cylinder	GHS pictogram(s)
2.2 Nonflammable Gas	2.2 Nonflammable Gas	2.2 Nonflammable Gas	2.2 Nonflammable Gas	Transportation label
H280	H281	H281	H280	Hazard statements
OSHA-H01	OSHA-H01	OSHA-H01	OSHA-H01	OSHA-required hazard statement
				CGA-required hazard statements
P202 P271+P403	P202 P271+P403 P282	P202 P271+P403 P282	P202 P271+P403	Prec. statements: prevention

P304, P340, P313	P304, P340, P313 P302, P336, P315	P304, P340, P313 P302, P336, P315	P304, P340, P313	Prec. statements: response
				Prec. statements: storage
				Prec. statements: disposal
OSHA-PG01	OSHA-PG01	OSHA-PG01	OSHA-PG01	OSHA-required precautionary statement
CGA-PG02 CGA-PG05 CGA-PG06 CGA-PG10 CGA-PG12 CGA-PG27	CGA-PG05 CGA-PG06 CGA-PG12 CGA-PG23 CGA-PG24 CGA-PG27	CGA-PG05 CGA-PG06 CGA-PG12 CGA-PG20 CGA-PG23 CGA-PG24 CGA-PG26 CGA-PG27	CGA-PG02 CGA-PG05 CGA-PG06 CGA-PG10 CGA-PG12 CGA-PG27	CGA-required precautionary statements

Oxygen, Refrigerated Liquid	Oxygen	Nitrous Oxide, Refrigerated Liquid	Nitrous Oxide	Gas name
7782-44-7	7782-44-7	10024-97-2	10024-97-2	CAS number
Gases underpressure Oxidizing gas	Gases underpressure Oxidizing gas	Gases underpressure Simple asphyxiant Oxidizing gas STOT SE dizziness/ drowsiness	Gases under pressure Simple asphyxiant Oxidizing gas STOT SE dizziness/ drowsiness	Hazard class
Refrigerated Liquefied gas Category 1	Compressed gas Category 1	Refrigerated Liquefied gas Category 1 Category 3	Liquefied gas Category 1 Category 3	Hazard category
Danger	Danger	Danger	Danger	Signal word

Gas cylinder Flame over circle	Gas cylinder Flame over circle	Gas cylinder Flame over circle Exclamationmark	Gas cylinder Flame over circle Exclamation mark	GHS pictogram(s)
2.2 Nonflammable Gas 5.1 Oxidizer	2.2 Nonflammable Gas 5.1 Oxidizer	2.2 Nonflammable Gas 5.1 Oxidizer	2.2 Nonflammable Gas 5.1 Oxidizer	Transportation label
H270H281	H270H280	H270H281H336	H270H280 H336	Hazard statements
		OSHA-H01	OSHA-H01	OSHA-required hazard statement
CGA-HG13		CGA-HG13	CGA-HG01	CGA-required hazard statements
P202 P220 P244 P271+P403 P282	P202 P220 P244 P271+P403	P202 P220 P244 P261 P271+P403 P282	P202 P220 P244 P261 P262 P271+P403 P280	Prec. statements: prevention
P370, P376 P302, P336, P315	P370, P376	P370, P376 P304, P340, P312 P302, P336, P315	P370, P376 P304, P340, P312 P302, P336, P315	Prec. statements: response
		P405	P405	Prec. statements: storage
		P501	P501	Prec. statements: disposal
OSHA-PG01	OSHA-PG01	OSHA-PG01	OSHA-PG01	OSHA-required precautionary statement
CGA-PG05 CGA-PG06 CGA-PG12 CGA-PG20 CGA-PG21 CGA-PG22 CGA-PG23 CGA-PG24 CGA-PG27 CGA-PG28	CGA-PG02 CGA-PG05 CGA-PG06 CGA-PG10 CGA-PG12 CGA-PG20 CGA-PG21 CGA-PG22 CGA-PG27	CGA-PG05 CGA-PG06 CGA-PG12 CGA-PG21 CGA-PG22 CGA-PG23 CGA-PG27 CGA-PG28	CGA-PG02 CGA-PG05 CGA-PG06 CGA-PG10 CGA-PG20 CGA-PG21 CGA-PG22 CGA-PG27	CGA-required precautionary statements

Annex E
CGA-recommended hazard and precautionary statements and rules
for their use
(Normative)

CGA developed hazard and precautionary statements, as shown in Tables E-1, to convey additional information or to further clarify the hazards and the rules for their use on labels and SDSs

Table E-1 Precautionary Statement Codes (PSCs), text, and rules for use

PSCs	STATEMENT	USED ON
OSHA-PG01	DO NOT REMOVE THIS PRODUCT LABEL (or equivalent wording).	Label
Rule for use: This OSHA precautionary statement is required on all products.		
CGA-PG02	Protect from sunlight when ambient temperature exceeds 52 °C (125 °F).	Label and SDS
Rule for use: This CGA precautionary statement is required on all gases except for those classified as refrigerated liquefied gases.		
CGA-PG05	Use a back flow preventive device in the piping.	Label and SDS
Rule for use: This CGA precautionary statement is required on all products.		
CGA-PG06	Close valve after each use and when empty.	Label and SDS
Rule for use: This CGA precautionary statement is required on all products.		
CGA-PG10	Use only with equipment rated for cylinder pressure.	Label and SDS
Rule for use: This CGA precautionary statement is required on all products with the Gas cylinder pictogram.		
This statement may be combined with CGA-PG20 into one that reads: "Use only with equipment of compatible materials of construction and rated for cylinder pressure."		
CGA-PG11	Never put cylinders into unventilated areas of passenger vehicles.	Label and

		SDS
Rule for use: This CGA precautionary statement is required on labels for carbon dioxide; carbon dioxide, refrigerated liquid; liquefied petroleum gas; acetylene; and propane. This CGA statement is used on SDSs for all flammable, pyrophoric, toxic, and refrigerated liquefied gases.		
CGA-PG12	Do not open valve until connected to equipment prepared for use.	Label and SDS
Rule for use: This CGA precautionary statement is required on all products.		
CGA-PG20	Use only equipment of compatible materials of construction.	Label and SDS
Rule for use: This CGA precautionary statement is required for DOT-classified corrosives (hazard class 8) and gases that have compatibility issues with materials used in gas handling systems. Known exceptions to its use are nonrefrigerated nitrogen and noble gases. This statement may be combined with CGA-PG10 into one that reads: "Use only with equipment of compatible materials of construction and rated for cylinder pressure." This statement may be combined with CGA-PG22 and CGA-PG32 into one that reads: "Use only with equipment constructed of compatible materials, cleaned for oxygen service and passivated before use."		
CGA-PG21	Open valve slowly.	Label and SDS
Rule for use: This CGA precautionary statement is required on oxidizing gases Category 1.		
CGA-PG22	Use only with equipment cleaned for oxygen service.	Label and SDS
Rule for use: This CGA precautionary statement is required on oxidizing gases Category 1. This statement may be combined with CGA-PG20 and CGA-PG32 into one that reads: "Use only with equipment constructed of compatible materials, cleaned for oxygen service and passivated before use."		
CGA-PG23	Always keep container in upright position.	Label and SDS
Rule for use: This CGA precautionary statement is required on refrigerated liquefied gases.		

CGA-PG24	DO NOT change or force fit connections.	Label and SDS
Rule for use: This CGA precautionary statement is required on refrigerated liquefied gases.		
CGA-PG26	Use insulated hoses and piping to avoid condensation of oxygen-rich liquid air.	Label and SDS
Rule for use: This CGA precautionary statement is required on helium, refrigerated liquid; hydrogen, refrigerated liquid; and neon, refrigerated liquid.		
CGA-PG27	Read and follow the Safety Data Sheet (SDS) before use.	Label
Rule for use: This CGA precautionary statement is required on all products.		
CGA-PG28	Avoid spills. Do not walk on or roll equipment over spills.	Label and SDS
Rule for use: This CGA precautionary statement is required on refrigerated liquefied oxygen and refrigerated nitrous oxide.		

Appendix F

Guide for use of 360 degree wrap around product identification for DOT-4L/TC-4LM and similar cylinders (Normative)

This Appendix contains the requirement for 360° wrap around product identification for DOT-4L/TC-4LM and similar cylinders designed for cryogenic liquids. This identification is in addition to the product label containing hazard warnings and precautionary information, and transportation symbols. It is also referred to in the compressed gas industry as a decal and in the medical gas industry as a label.

Appendix F does not apply to:

- a) Large cryogenic vessels permanently mounted in vehicles;
- b) Small liquid oxygen cryogenic units used by patients for medical purposes; or
- c) Open topped nitrogen dewars.

F.1 General recommendations

F.1.1 Each container designed for cryogenic liquids, except those described previously as non-applicable, should be marked with a 360 degree wrap around product identification to identify its contents. The identification should be marked continuously with the liquid product identification.

F.1.2 The identification should be sized (minimum 51 mm [2 in] high letters) and spaced so that it is visible from all sides when not obstructed. Placement should be horizontal and just below the upper circumferential weld adhering to the cylinder sidewall. See Figure F-1 for an illustration of the decal (oxygen is used as an example).

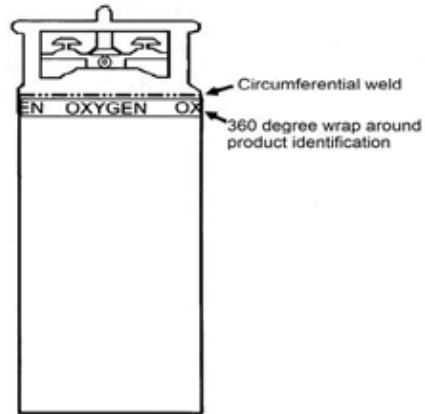


Figure F-1: Example of industrial cryogenic identification

F.1.3 Portable cryogenic medical gas containers utilizing 360° wrap around decals as labels with the text shown in Table F-1 as appropriate are compliant with applicable regulations.

F.1.4 Table F-1 lists the color options for each medical gas. Either color option may be selected with 360° wrap around label wording.

Table F-1: Color coding for portable cryogenic medical gas containers

Medical gas	Color (select one)	360 degrees wrap around label wording(select one)
Carbon dioxide	Gray lettering on white background; or White lettering on gray background	MEDICAL CARBON DIOXIDE; or CARBON DIOXIDE USP
Nitrogen	Black lettering on white background; or White lettering on black background	MEDICAL NITROGEN; or NITROGEN NF
Nitrous oxide	Blue lettering on white background; or White lettering on blue background	MEDICAL NITROUS OXIDE; or NITROUS OXIDE USP
Oxygen	Green lettering on white background; or White lettering on green background	MEDICAL OXYGEN; or OXYGEN USP


Appendix G

Hazard and precautionary statements and codes (Normative)

Table G-1 lists the hazard statements identified by code designations in Appendices D and E with their associated signal word, pictogram, and precautionary statement codes.

Table G-2 lists the precautionary statements as identified by code designations in Appendix D and Table G-1.

Table G-1: Hazard Statement Codes (HSC) and associated label elements

HSC	Hazard statement	Signal word	Pictogram	Associated precautionary statement codes ¹⁾
GHS Physical hazards				
H270	MAY CAUSE OR INTENSIFY FIRE; OXIDIZER	DANGER		P202; P220; P244; P370, P376; P271+P403; CGA-PG10; CGA-PG21; CGA-PG22




H280	CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED	WARNING		P202; P271+P403; CGA-PG10; CGA-PG02
H281	CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY	WARNING		P202; P282; P302, P336, P315; P403; CGA-PG10; CGA-PG21; CGA-PG22
GHS Health hazards				
H336	MAY CAUSE DROWSINESS OR DIZZINESS	WARNING		P202; P233 ²⁾ ; P261; P304, P340, P312; P271+P403; P405; P501

Table G-2—Precautionary statement codes and text

Precautionary statement code	Statement
Required on all labels	
OSHA-PG01	DO NOT REMOVE THIS PRODUCT LABEL (or equivalent wording)
P202	Do not handle until all safety precautions have been read and understood.
CGA-PG05	Use a back flow preventive device in the piping.
CGA-PG06	Close valve after each use and when empty.
CGA-PG12	Do not open valve until connected to equipment prepared for use.
CGA-PG27	Read and follow the Safety Data Sheet (SDS) before use.
Prevention (GHS)	
P220	Keep and store away from clothing and other combustible materials.
P244	Keep valves and fittings free from grease and oil.
P261	Avoid breathing gas.
P262	Do not get in eyes, on skin, or on clothing.
P271+P403	Use and store only outdoors or in a well-ventilated place.
P280	Wear protective gloves, protective clothing, and either eye or face protection.
P282	Wear cold insulating gloves, face shield, and eye protection.
Prevention (CGA)	
CGA-PG10	Use only with equipment rated for cylinder pressure.
CGA-PG17	Use only with equipment purged with inert gas or evacuated prior to

	discharge from cylinder.
CGA-PG20	Use only equipment of compatible materials of construction.
CGA-PG21	Open valve slowly.
CGA-PG22	Use only with equipment cleaned for oxygen service.
CGA-PG24	DO NOT change or force fit connections.
CGA-PG26	Use insulated hoses and piping to avoid condensation of oxygen-rich liquid air.
CGA-PG28	Avoid spills. Do not walk on or roll equipment over spills.
Response (GHS)	
P302	IF ON SKIN:
P304	IF INHALED:
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P313	Get medical advice/attention.
P315	Get immediate medical advice/attention.
P336	Thaw frosted parts with lukewarm water. Do not rub affected area.
P340	Remove person to fresh air and keep comfortable for breathing.
P370	In case of fire:
P376	Stop leak if safe to do so.
Storage (GHS)	
P405	Store locked up.
Storage (CGA)	
CGA-PG02	Protect from sunlight when ambient temperature exceeds 52°C (125°F).
CGA-PG11	Never put cylinders into unventilated areas of passenger vehicles.
CGA-PG23	Always keep container in upright position.
Disposal (GHS)	
P501	Dispose of contents/container in accordance with container supplier/owner instructions.
2) This statement is to be used if immediate specific measures are required in accordance with OSHA's Hazard Communication Standard, Appendix C.4.3.	

Annex H
CGA-recommended hazard and precautionary statements and rules
for their use (Normative)

CGA developed hazard and precautionary statements, as shown in Tables H-1 and H-2, to convey additional information or to further clarify the hazards and the rules for their use on labels and SDSs.

Table H-1: Hazard statement codes, text, and rules for use

HSC	STATEMENT	USED ON
OSHA-H01	MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION	Label and SDS
Rule for use: This OSHA hazard statement is required on any products with a hazard class of "Gases under pressure" and no classification for health hazards. This hazard statement is not used on pyrophorics, compressed air, oxygen/oxygen refrigerated, or oxygen mixtures with the oxygen concentration greater than 19.5%.		
CGA-HG01	MAY CAUSE FROSTBITE	Label and SDS
Rule for use: This CGA hazard statement is used on liquefied gases including toxics based on the state of gas because exposure to the gas and its latent heat energy transfer is what causes frostbite.		
CGA-HG03	MAY INCREASE RESPIRATION AND HEART RATE.	Label and SDS
Rule for use: This CGA hazard statement is used on carbon dioxide and gas mixtures containing greater than or equal to 2% carbon dioxide.		
CGA-HG13	COMBUSTIBLES IN CONTACT WITH OXIDIZING REFRIGERATED LIQUIDS MAY EXPLODE ON IGNITION OR IMPACT	Label and SDS
Rule for use: This CGA hazard statement is used on oxygen, refrigerated liquid, and nitrous oxide, refrigerated liquid.		
CGA-HG24	SUPPORTS COMBUSTION	Label and SDS
Rule for use: This CGA hazard statement is only used on compressed air.		

MADE by the Minister responsible for the Bureau of Standards this 13th day of October, 2023.



(HON. JOSE ABELARDO MAI)

Minister of Agriculture, Food Security and Enterprise
(Minister responsible for Bureau of Standards)

