



# **LABELLING OF MEDICAL GAS CONTAINERS**

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**Table of Contents**

1	Introduction .....	1
2	Scope and Purpose .....	1
2.1	Scope .....	1
2.2	Purpose .....	1
3	Definitions .....	1
4	Labels .....	2
4.1	Types of labels .....	2
4.2	Label design .....	2
4.2.1	Batch label .....	2
4.2.2	Product identification label .....	2
4.2.3	Patient Information Leaflet (PIL) .....	3
4.3	Label design specifications .....	3
4.4	Label control .....	3
4.5	Label placement .....	3
4.5.1	Loose cylinder/bundles/liquid gas cylinder .....	3
4.5.2	Other containers .....	4
5	References .....	4
	Appendix A - List of commonly used medical gases and gas mixtures .....	5
	Appendix B - Examples of labels and label placement .....	6

## 1 Introduction

This publication provides detailed guidelines on the labelling of medical gas containers, one of the core elements of Good Manufacturing Practice (GMP). This document serves as a supplemental reference to AIGA 023 'Good Manufacturing Guide for Medicinal Gases' and Position Paper PP-01 'GMP Guide for Medicinal Gases'.

Regulatory requirements for the country of operation shall also be followed.

## 2 Scope and Purpose

### 2.1 Scope

This document covers the content, usage and placement of labels on all medical gas containers. Medical gas containers include:

- Cylinders
- Cylinder bundles or pallets
- Portable cryogenic liquid containers, including pressurized liquefied gas containers (liquid cylinders and dewars)
- Road tankers and ISO containers for cryogenic and refrigerated gas storage
- Liquid storage tanks

### 2.2 Purpose

To specify the content requirements of medical gas container labels and to provide examples of how these labels are attached to the medical gas containers.

## 3 Definitions

**GMP** (Good Manufacturing Practice) – That part of Quality Assurance which ensures that medicinal gases are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation or product specification.

**GHS** (Globally Harmonized System of Classification and Labelling of Chemicals) – A system for standardizing and harmonizing the classification and labelling of chemicals.

**Medical Device Gas** – A gas that is used to support medical procedures by operating medical-surgical tools, equipment booms, pendants and similar medical support applications.

**Medical Gas** – A gas that is manufactured or stored in a liquefied, non-liquefied, or cryogenic state; and is administered as a drug or used as a power source for medical equipment or for testing medical equipment.

The term Medical Gas covers both Medicinal Gas and Medical Device Gas. (Refer to Appendix A for more information.)

**Medicinal Gas** – Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes using pharmacological action.

**Pharmacopoeia** – An authoritative published book (or list) of medicinal drugs, describing their preparation including specification and analytical methods, and their use.

**PIL (Patient Information Leaflet)** – A leaflet supplied by the manufacturer of a licensed medicine to the patient. PILs contain specific information about medical conditions, doses and side effects of the product.

**Terminology:**

Can – Indicates a possibility or ability.

May – Indicates that the procedure is optional.

Need Not – Indicates that the procedure is optional.

Shall – Indicates that the procedure is mandatory. It is used wherever the criteria for conformance to specific recommendations allow no deviation.

Should – Indicates that a procedure is recommended.

## **4 Labels**

### **4.1 Types of labels**

The types of labels include:

- Batch label
- Product identification label
- Package insert label such as Patient Information Leaflet (PIL), where required by the local authority

### **4.2 Label design**

#### **4.2.1 Batch label**

The batch label shall include:

- Batch number
- Production / fill date
- Expiry date (if required)
- Contact details of person in charge of the product (if required)
- Product name (unless other labels include it)
- Quantity (unless other labels include it)

#### **4.2.2 Product identification label**

The product identification labels shall comply with national regulatory requirements. For countries where GHS is implemented, the labels shall comply with GHS requirements.

The product identification label shall include:

- Product identifier
- Hazard label or pictogram,
- Hazard statement
- Precautionary statement
- Supplier information
- Label design change or revision information

### 4.2.3 Patient Information Leaflet (PIL)

The Patient Information Leaflet shall include:

- Name of product
- Pharmaceutical form and content by weight, by volume or by number of doses of the product
- The method and, if necessary, the route of administration
- Instructions for use / dosage
- Caution / special warning
- Special storage precautions
- Pharmacopoeia standard
- Drug registration number
- Name and address of the holder of the authorization for placing the product on the market

**Note:** A PIL for medicinal gas is not mandatory unless stipulated by the regulatory authority within the country. A PIL would typically be required if the medicinal gas is registered as a pharmaceutical product. PIL is also referred to as “Package Insert” or “Package Leaflet”.

### 4.3 Label design specifications

The design process for labels shall carefully consider these factors:

- The size and shape of the label shall be appropriate for its intended purposes.
- Appropriate placement of the label to ensure access and visibility to all users.
- The durability of label materials, including adhesives and ties, to withstand wear and tear in use, shall be consistent with the shelf life of the product.
- Any paint used shall be resistant to chemicals, water, sunlight and wear and tear during use.
- Labels requiring data entry shall be able to accept ink/print.
- Effective date of the new design.
- Language appropriate to the country of use.

### 4.4 Label control

Label control and accountability processes shall be in place to ensure that:

- Medical gas container labels are current and correct.
- Medical gas container labels are not inadvertently mixed with industrial labels.
- Medical gas container labels are inventoried and the quantity of labels used is reconciled against the quantity removed from inventory.
- Refer to AIGA 023 GMP ‘Guide for Medicinal Gases’ for the appropriate actions needed for the receipt, storage, issue, fitting and control of labels supplied with the medical gas containers.

### 4.5 Label placement

#### 4.5.1 Loose cylinder/bundles/liquid gas cylinder

Every loose cylinder, bundle, or liquid gas cylinder shall be correctly labelled to conform with national or international (e.g. GHS) requirements. The product pharmacopoeia purity/grade, batch number, production date and expiry date may be displayed on a separate label.

The preferred placement of the product identification label and the batch label is shown in Appendix B.

#### 4.5.2 Other containers

Product identification labels for other containers such as bulk liquid tankers, ISO containers and liquid storage tanks should be placed in a prominent position, either on the bodies of the containers or on metal panels affixed to the containers.

For liquid containers, the Certificate of Conformance (CoC) or Certificate of Analysis (CoA) will serve as the batch label.

For information on the placement of the labels, refer to Appendix B.

For more information on the appropriate sizes of product identification labels, refer to AIGA 017.

### 5 References

- (1) AIGA 017 - 'Labelling of Gas Containers (and associated equipment)'. Asia Industrial Gases Association, [www.asiaiga.org](http://www.asiaiga.org)
- (2) AIGA 023 – 'Good Manufacturing Practice Guide for Medicinal Gases'. Asia Industrial Gases Association, [www.asiaiga.org](http://www.asiaiga.org)
- (3) AIGA Position Paper PP-01 - 'GMP Guide for Medicinal Gases'. Asia Industrial Gases Association, [www.asiaiga.org](http://www.asiaiga.org)
- (4) Directive 2001/83/EC: Community Code relating to Medicinal Products for Human Use
- (5) EIGA Leaflet (1-12-2010) New Requirements for the Labelling of Gas Cylinders. European Industrial Gases Association, [www.eiga.eu](http://www.eiga.eu)
- (6) United Nations (UN) publication: 'Globally Harmonized System (GHS) of Classification and Labelling of Chemicals', also called the 'Purple Book'.  
[http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs\\_rev04/English/ST-SG-AC10-30-Rev4e.pdf?bcsi\\_scan\\_3C2C63D4BDF20DBB=0&bcsi\\_scan\\_filename=ST-SG-AC10-30-Rev4e.pdf](http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf?bcsi_scan_3C2C63D4BDF20DBB=0&bcsi_scan_filename=ST-SG-AC10-30-Rev4e.pdf)

**Appendix A - List of commonly used medical gases and gas mixtures**

	<b>Gas Name*</b>	<b>Chemical Formulae</b>
1.	Medical oxygen	O <sub>2</sub>
2.	Nitrous oxide	N <sub>2</sub> O
3.	Nitrogen	N <sub>2</sub>
4.	97% nitrogen	N <sub>2</sub>
5.	Low oxygen nitrogen	N <sub>2</sub>
6.	Carbon dioxide	CO <sub>2</sub>
7.	Medical air	–
8.	Synthetic medical air	N <sub>2</sub> , O <sub>2</sub>
9.	Nitric oxide	NO
10.	Argon	Ar
11.	Carbon monoxide	CO
12.	50% nitrous oxide, 50% medical oxygen	N <sub>2</sub> O, O <sub>2</sub>
13.	Medical oxygen & carbon dioxide mixture	O <sub>2</sub> , CO <sub>2</sub>
14.	Helium & medical oxygen mixture	He, O <sub>2</sub>

\* Subject to country pharmacopoeias, if any



## Appendix B - Examples of labels and label placement

### 1. Batch label

Batch label information required:

- **Batch number**
- **Production/fill date**
  
- *Expiry date (if required)*
- *Contact details of person in charge of the product*
- *Product name (unless other labels include it)*
- *Quantity (unless other labels include it)*

*Italics indicate optional items that may be required by regulations*

Sample label:

<b>Batch number:</b>	MO2-20131210-A-01
<b>Production/fill date:</b>	2013-12-10
Expiry date:	2018-12-10
Person in charge of product:	John Tan, 22223333
Product name:	Medical Oxygen
Quantity:	7.2 m <sup>3</sup>


## 2. Product identification label

Product identification label information required:


- Product identifier
- Hazard label/pictogram
- Hazard statement
- Precautionary statement
- Supplier information
- Label design change or revision information

Sample label:

**Medical Oxygen, UN1072**



Gases Under Pressure - Gas released may be very cold. Gas container may explode if heated.



Oxidizers - Can burn without air, or can intensify fire in combustible materials.

**Hazard statement:**

- May cause or intensify fire
- Contains gas under pressure; may explode if heated

**Precautionary statement:**

- Keep away from clothing or other combustible materials
- Keep reduction valves free from grease or oil
- In case of fire, stop leak if safe to do so
- Protect from sunlight; store in well ventilated place

**Supplier information:**  
 ABC Pty Ltd.,  
 No 1 Main Street, 2300 State XYZ, Phone Number

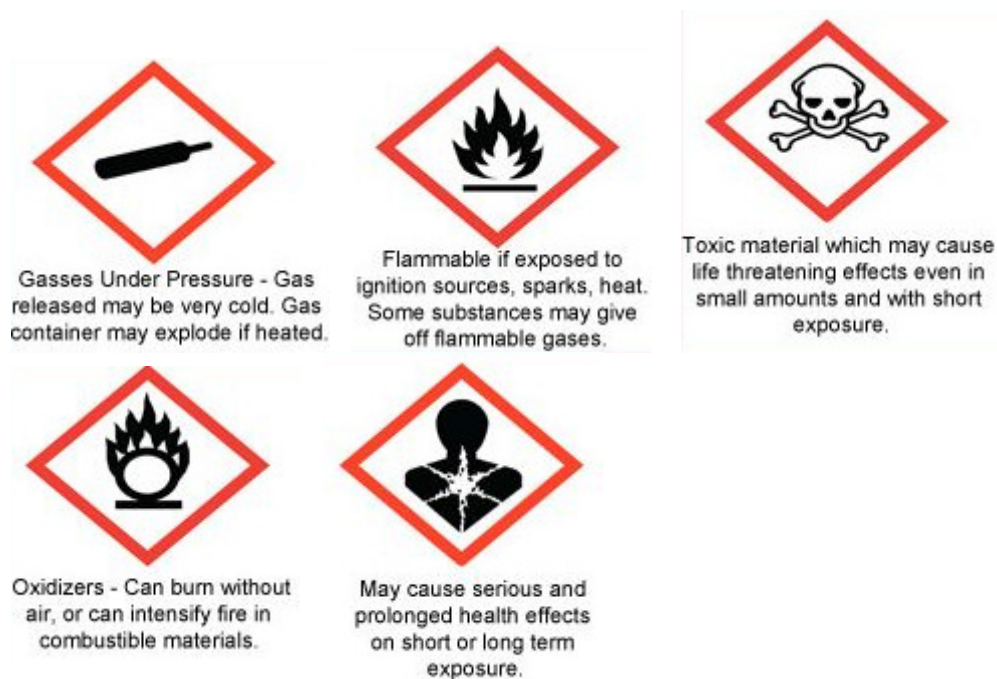
Label design change or revision information: LbIMO2/r2/2013-1

Refer to 'Examples of hazard pictograms'

Refer to 'Examples of hazard statements'

Refer to 'Examples of precautionary statements'

Examples of hazard pictograms associated with medical gases:



Examples of hazard statements associated with medical gases:

- May cause or intensify fire
- Contains gas under pressure; may explode if heated
- May cause drowsiness or dizziness
- Fatal if inhaled

Examples of precautionary statements associated with medical gases:

- Keep away from clothing and other combustible materials
- Protect from sunlight. Store in well-ventilated place.
- Keep reduction valves free from grease and oil
- Avoid release to the environment
- Wear respiratory protection
- Do not eat, drink or smoke when using this product
- If exposed or concerned: get medical advice/attention
- Dispose in accordance with all applicable regulations

### 3. Label placement on gas containers and packages

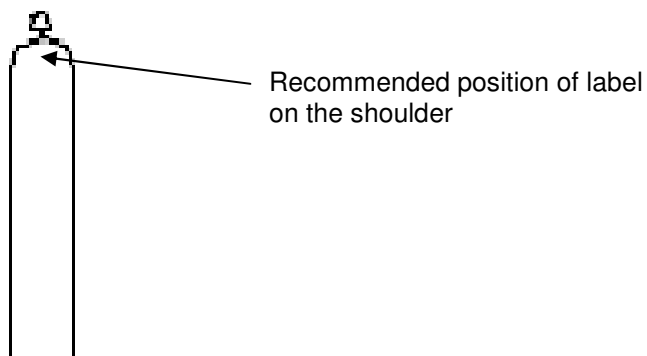


Figure 1: Loose cylinder

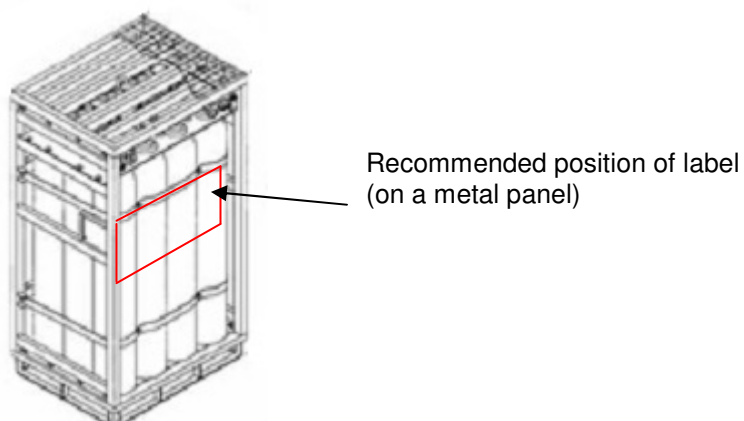


Figure 2: Cylinder bundle

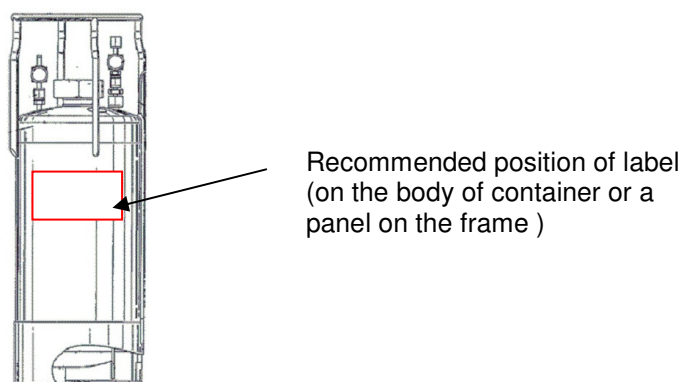
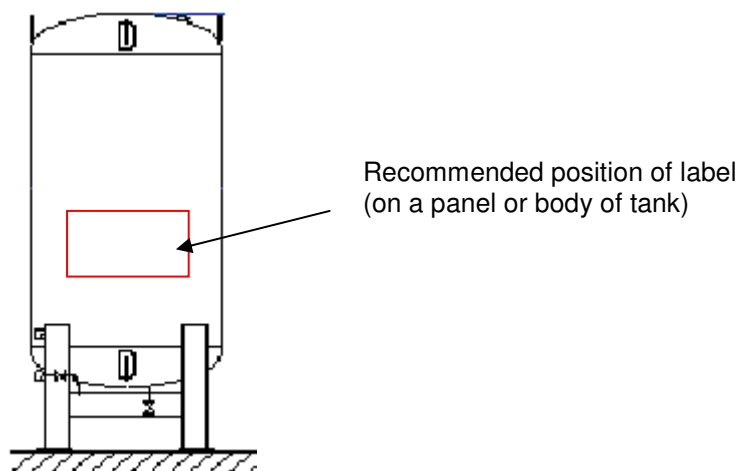
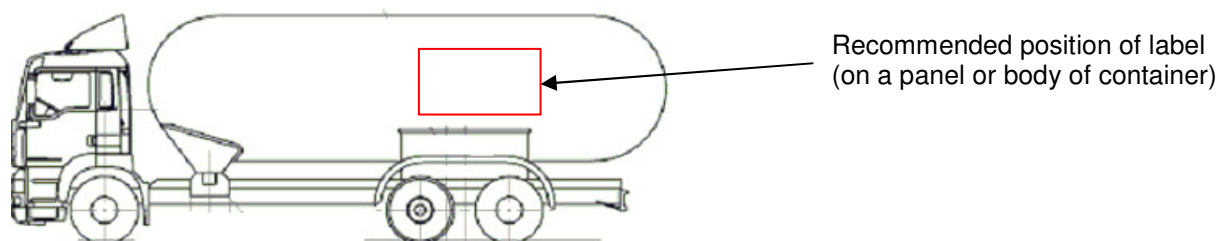


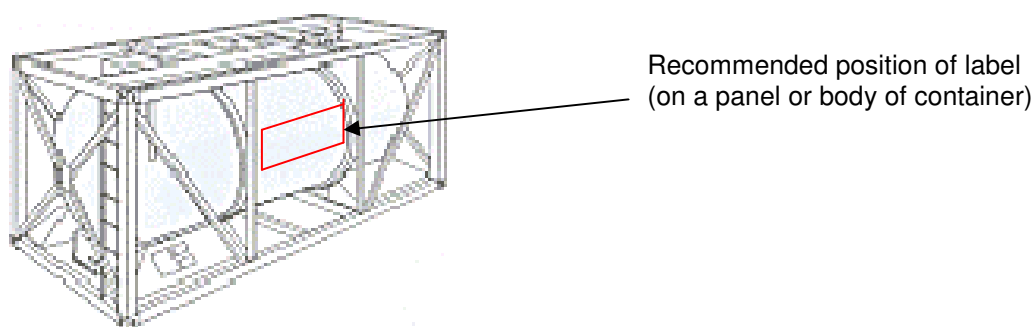
Figure 3: Portable Liquid Container (PLC)



**Figure 4: Liquid Storage tank**



**Figure 5: Bulk liquid tanker**



**Figure 6: Bulk liquid ISO container**