

OXYGEN- oxygen gas
Indiana Oxygen Company Inc

Oxygen

OXYGEN COMPRESSED LABEL

OXYGEN COMPRESSED USP

UN 1072

OXYGEN 2

(R-K14) 114619

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 in conjunction with resuscitative equipment. **Produced by Air Liquefaction.**

DANGER: MAY CAUSE OR INTENSIFY FIRE; OXIDIZER, CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. Open valve slowly. Close valve after each use and when empty. Protect from sunlight and when the ambient temperature exceeds 52°C (125°F). Read and follow the Safety Data Sheet (SDS) before use. CAS: 7782-44-7 DO NOT REMOVE THIS PRODUCT LABEL.

INDIANA OXYGEN COMPANY

6099 West Corporate Way, Indianapolis, IN 462278

317-290-0003

CONTENTS:

LTRS: _____ CU. FT. _____



OXYGEN COMPRESSED USP
UN 1072
OXYGEN 2
 (R-K14) 114621

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 in conjunction with resuscitative equipment. **Produced by Air Liquefaction.**

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INDIANA OXYGEN COMPANY

6099 West Corporate Way, Indianapolis, IN 46228
317-290-0003

CONTENTS:

LTRS: _____ CU. FT. _____



OXYGEN COMPRESSED USP
UN 1072
C.A.S. NO. 7782-44-7

Contents _____ LTRS. _____ CU. FT. _____

OXYGEN 2
(R-K14) 11623

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

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INDIANA OXYGEN COMPANY

6099 West Corporate Way, Indianapolis, IN 462278

317-290-0003

**OXYGEN,
COMPRESSED
USP
UN 1072**

C.A.S. NO. 7782-44-7



Contents _____ LTRS.
CU. FT.

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INDIANA OXYGEN COMPANY
6099 West Corporate Way, Indianapolis, IN 46278
317-290-0003



**OXYGEN COMPRESSED USP
UN 1072
C.A.S. NO. 7782-44-7**

OXYGEN 2
(R-K14) 114919

INDIANA OXYGEN COMPANY
6099 West Corporate Way, Indianapolis, IN 462278
317-290-0003

DANGER: MAY CAUSE OR INTENSIFY FIRE; OXIDIZER, CONTAINS GAS UNDER

PRESSURE; MAY EXPLODE IF HEATED. Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. Open valve slowly. Close valve after each use and when empty. Protect from sunlight and when the ambient temperature exceeds 52°C (125°F). Read and follow the Safety Data Sheet (SDS) before use. DO NOT REMOVE THIS PRODUCT LABEL.

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Produced by Air Liquefaction.

| CYLINDER TYPE | LITERS | CYLINDER TYPE | LITERS |
|----------------------|---------------|----------------------|---------------|
| R | 570 | M9 | 255 |
| E | 660 | M6 | 170 |
| D | 400 | Other | _____ |

**OXYGEN,
COMPRESSED
USP
UN 1072**

C.A.S. NO. 7782-44-7



**INDIANA OXYGEN
COMPANY**

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Indianapolis, IN 46278

317-290-0003



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| CYLINDER TYPE | LITERS | | CYLINDER TYPE | LITERS | |
|---------------|--------|--------------------------|---------------|--------|--------------------------|
| R | 570 | <input type="checkbox"/> | M9 | 255 | <input type="checkbox"/> |
| E | 660 | <input type="checkbox"/> | M6 | 170 | <input type="checkbox"/> |
| D | 400 | <input type="checkbox"/> | Other | _____ | |

**OXYGEN,
COMPRESSED
USP
UN 1072**

C.A.S. NO. 7782-44-7



**INDIANA OXYGEN
COMPANY**

6000 West Corporate Way



0033 West Corporate Way
Indianapolis, IN 46278
317-290-0003



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Produced by Air Liquefaction.

| CYLINDER TYPE | LITERS | | CYLINDER TYPE | LITERS | |
|----------------------|---------------|--------------------------|----------------------|---------------|--------------------------|
| R | 570 | <input type="checkbox"/> | M9 | 255 | <input type="checkbox"/> |
| E | 660 | <input type="checkbox"/> | M6 | 170 | <input type="checkbox"/> |
| D | 400 | <input type="checkbox"/> | Other | _____ | |

OXYGEN REFRIGERATED LABEL

REFRIGERATED LIQUID

**OXYGEN,
REFRIGERATED
LIQUID
USP**

UN 1073

**OXYGEN 2
(R-K14) 115073**

**↑ ALWAYS KEEP CONTAINER IN UPRIGHT POSITION. ↑
DO NOT CHANGE OR FORCE FIT CONNECTIONS.**

CONTENTS: PG OXURM 164610
(LITERS) PG OX35OM 145522

WARNING:USP 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 in conjunction with resuscitative equipment.

Produced by Air Liquefaction.

DANGER: MAY CAUSE OR INTENSIFY FIRE: OXIDIZER.
CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY
COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT.

Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. Wear cold insulating gloves, face shield and eye protection. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. DO NOT change of force fit connections. Avoid spills. Do not walk or roll equipment over spills. Close valve after each use and when empty. Always keep container in upright position. Read and follow the Safety Data Sheet (SDS) before use.

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

CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL.

INDIANA OXYGEN COMPANY

6099 West Corporate Way, Indianapolis, IN 462278

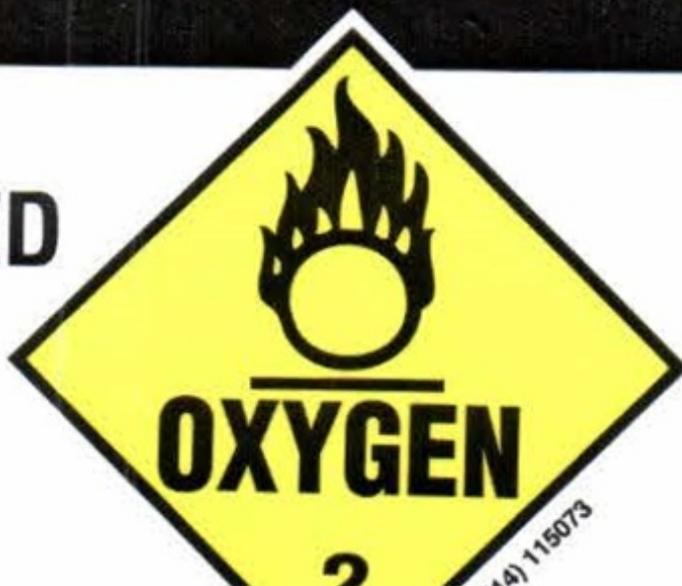
317-290-0003

REFRIGERATED LIQUID

**OXYGEN,
REFRIGERATED
LIQUID**

USP

UIN1073





↑ ALWAYS KEEP CONTAINER IN UPRIGHT POSITION. ↑
DO NOT CHANGE OR FORCE FIT CONNECTIONS.

| | | | |
|-----------|-----------|--------|--------------------------|
| CONTENTS: | PG OXURM | 164610 | <input type="checkbox"/> |
| (LITERS) | PG OX350M | 145522 | <input type="checkbox"/> |
| OTHER: | | | <input type="checkbox"/> |

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Produced by Air Liquefaction.

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 CONTAINS REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY.
 COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT.

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CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL.

INDIANA OXYGEN COMPANY

6099 West Corporate Way

Indianapolis, IN 46278

317-290-0003



OXYGEN CERTIFICATE OF ANALYSIS

Certificate of Analysis - Oxygen USP

CUSTOMER _____ VENDOR / SUPPLIER _____

Indiana Oxygen Co
6099 W Corporate Way
Indianapolis, IN 46278

THIS LETTER IS TO PROVIDE YOU WITH THE CERTIFICATION YOU REQUESTED FOR OXYGEN USP LOT # _____ SUPPLIED TO YOU IN CYLINDERS / VESSELS BY OUR LOCATION.

These cylinders were filled in accordance with the Standard Operating Procedures utilized for the manufacture of Medical Gases. By following these procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Practices (cGMP) Regulations.

CAUTION: VENDOR SUPPLIES THIS CERTIFICATION TO CUSTOMER TO ASSIST CUSTOMER IN ENSURING COMPLIANCE WITH 21 CFR 211.84. THIS CERTIFICATION DOES NOT ELIMINATE CUSTOMER'S OBLIGATION TO COMPLY WITH OTHER PORTIONS OF 21 CFR 210 AND 211, INCLUDING BUT NOT LIMITED TO 21 CFR 211.165 (FINISHED PRODUCT TESTING) FOR CYLINDERS AND VESSELS FILLED FROM THESE SUPPLY CYLINDERS. THESE CYLINDERS ARE NOT CERTIFIED FOR INSTRUMENT CALIBRATION.

| TEST REQUIREMENT | USP SPECIFICATION | LOT ANALYSIS |
|------------------|--------------------|--------------|
| IDENTIFICATION | PASS | |
| ODOR | PASS | |
| CARBON DIOXIDE | LESS THAN 0.03% | |
| CARBON MONOXIDE | LESS THAN 0.001% | |
| ASSAY | GREATER THAN 99.0% | |

* **NOTE:** The USP/NF exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from the tests for Carbon Dioxide and Carbon Monoxide. As our label states, the Oxygen USP being supplied is manufactured by the Air Liquefaction Process.

The methodology being used to perform the USP / NF Test for Assay is indicated below:

Paramagnetic Analyzer Model # _____

Supplier Signature _____

Date _____



Post Office Box 28588
Indianapolis, Indiana 46228
(317) 290-0003

Certificate of Analysis - Oxygen USP

Customer

Vendor / Supplier

Indiana Oxygen Co

6099 W Corporate Way

Indianapolis, IN 46278

This letter is to provide you with the Certification you requested for Oxygen, USP, Lot # _____
Supplied to you in cylinders / vessels by our location.

These cylinders were filled in accordance with the Standard Operating Procedures utilized for the manufacture of Medical Gases. By following these procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Practices (cGMP) Regulations.

CAUTION: Vendor supplies this certification to customer to assist customer in ensuring compliance with 21 CFR 211.84. This certification does not eliminate customer's obligation to comply with other portions of 21 CFR 210 & 211 including but not limited to 21 CFR 211.265 (finished product testing) for cylinders and vessels filled from these supply cylinders. These cylinders are not certified for instrument calibration purposes.

| Test / Requirement | USP Specification | Lot Analysis |
|--------------------|-------------------|--------------|
| Identification | Pass | |
| Odor | Pass | |
| Carbon Dioxide | ≤ 0.03 % | * |
| Carbon Monoxide | < 0.001 % | * |
| Assay | > 99.0 % | |

* **NOTE:** The USP/NF exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from the tests for Carbon Dioxide and Carbon Monoxide. As our label states, the Oxygen USP being supplied is manufactured by the Air Liquefaction Process.

The methodology being used to perform the USP / NF Test for Assay is indicated below:

Paramagnetic Analyzer Model # _____

Supplier Signature _____ Date _____

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:48546-0001 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 99 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:48546-0001-1 | 113 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 2 | NDC:48546-0001-2 | 170 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 3 | NDC:48546-0001-3 | 255 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 4 | NDC:48546-0001-4 | 425 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 5 | NDC:48546-0001-5 | 566 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 6 | NDC:48546-0001-6 | 679 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 7 | NDC:48546-0001-7 | 1132 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 8 | NDC:48546-0001-8 | 3114 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |
| 9 | NDC:48546-0001-9 | 4247 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1960 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| NDA | NDA205767 | 01/01/1960 | |

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:48546-0002 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 99.5 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:48546-0002-1 | 6228 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 2 | NDC:48546-0002-2 | 9540 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 3 | NDC:48546-0002-3 | 164793 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 4 | NDC:48546-0002-4 | 164734 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 5 | NDC:48546-0002-5 | 145632 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 6 | NDC:48546-0002-6 | 127350 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 7 | NDC:48546-0002-7 | 164734 L in 1 DEWAR; Type 0: Not a Combination Product | 01/01/1961 | |
| 8 | NDC:48546-0002-8 | 420 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 9 | NDC:48546-0002-9 | 690 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA205767 | 01/01/1961 | |

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:48546-0004 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 99.6 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:48546-0004-1 | 570 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 2 | NDC:48546-0004-2 | 3470 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 3 | NDC:48546-0004-3 | 6900 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 4 | NDC:48546-0004-4 | 7760 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 5 | NDC:48546-0004-5 | 9340 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 6 | NDC:48546-0004-6 | 164.5 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 7 | NDC:48546-0004-7 | 139 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 8 | NDC:48546-0004-8 | 248.4 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 9 | NDC:48546-0004-9 | 623 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA205767 | 01/01/1961 | |

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:48546-0006 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 99 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:48546-0006-1 | 4248 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |
| 2 | NDC:48546-0006-2 | 1133 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1961 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA205767 | 01/01/1961 | |

Labeler - Indiana Oxygen Company Inc (006036776)

Registrant - Indiana Oxygen Company Inc (006036776)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---|
| Indiana Oxygen Company Inc | | 006036776 | manufacture(48546-0001, 48546-0002, 48546-0004, 48546-0006) |

Revised: 10/2023

Indiana Oxygen Company Inc