

**OXYGEN- oxygen gas**  
**Roberts Oxygen Company, Inc.**

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**OXYGEN REFRIGERATED LIQUID, USP-045**

**ROBERTS OXYGEN**  
**ROCKVILLE, MARYLAND 20866**  
**TEL: (301) 948-8100**

**CERTIFICATE OF ANALYSIS**  
**OXYGEN REFRIGERATED LIQUID, USP\***  
**PRODUCED BY AIR-LIQUEFACTION PROCESS**

**TRAILER#:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

**LOT#:** \_\_\_\_\_

\*USP applies only when used in a medical application or by medical customers properly registered with the FDA.

**Component Test Method Limit Result**

**Oxygen** \_\_\_\_\_ **>99.5%** \_\_\_\_\_

**Odor ORGANOLEPTIC N/D** \_\_\_\_\_

\_\_\_\_\_  
Product is identified as OXYGEN, USP through process validations, dedicated piping, and product specific connections.

Notes: \_\_\_\_\_

RELEASED BY: \_\_\_\_\_

SIGNATURE

RELEASED BY: \_\_\_\_\_

PRINTED NAME

Printed & Published by J.J. KELLER & ASSOCIATES, INC., Neenah, WI \* USP

(800) 327-6868 \*jkkeller.com \* Printer in the United States



oxygen gas

### Product Information

|                                |                          |                           |               |
|--------------------------------|--------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG  | <b>Item Code (Source)</b> | NDC:46123-045 |
| <b>Route of Administration</b> | RESPIRATORY (INHALATION) |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>                                      | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OXYGEN</b> (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN                   | 990 mL in 1 L   |

### Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                       | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:46123-045-01 | 1 L in 1 TANK; Type 0: Not a Combination Product | 01/01/2014                  |                           |

### Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| NDA                       | NDA205849                                       | 01/01/2014                  |                           |

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

### Establishment

| <b>Name</b>                  | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|------------------------------|----------------|---------------|----------------------------|
| Roberts Oxygen Company, Inc. |                | 791818008     | manufacture(46123-045)     |

Revised: 11/2023

Roberts Oxygen Company, Inc.