

**NITROGEN - nitrogen gas**  
**Air Liquide Large Industries U.S. LP**

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**Nitrogen NF Bulk Liquid**

**Nitrogen N.F. COA**

**AIR LIQUIDE NITROGEN N.F.**

Form Number: 2A-ALL-QUA-0003-F

Revision: 0

Effective Date: 03/02/06

Page: 1/1

CERTIFICATE OF ANALYSIS

Air Liquide large Industries U.S. L.P. - Houston, TX 77056

PRODUCED BY AIR LIQUEFACTION

1. Location Street Address1

2. Carrier \_\_\_\_\_

Street Address 2

City, State Zip

3. Lot Number \_\_\_\_\_

4. Trailer No \_\_\_\_\_

**PRE-FILL REPORT**

5. Residual Assay 6. Odor  
product per appropriate

( $\leq 10$  ppm O<sub>2</sub>) Detected

\_\_\_\_\_ ppm Yes No

\_\_\_\_\_

Initial

Initial

**FILL REPORT**

7. Trailer loaded with appropriate

loading procedure by:

Signature \_\_\_\_\_

Date \_\_\_\_\_

**ANALYSIS REPORT**

Test required  
Results

Method of Analysis

Specifications

ASSAY AND  
10. \_\_\_\_\_%

8. PARAMAGNETIC \_\_\_\_\_

99.998% N<sub>2</sub> Minimum\*

IDENTIFICATION

MICROFUEL CELL \_\_\_\_\_

ELECTROCHEMICAL \_\_\_\_\_

CELL

10 ppm O<sub>2</sub> Maximum

11.

\_\_\_\_\_ ppm

9. Analyzer Tag Number

12. DETECTPR TUBE

10 ppm CO Maximum

14. \_\_\_\_\_ppm

CARBON

INFARED ANALYZER \_\_\_\_\_

Expiration Date of Tube

15. \_\_\_\_\_

MONOXIDE

Lot Number of Tube

16. \_\_\_\_\_

13. Analyzer Tag Number

ODOR

Organoleptic (Nasal)

None

17. \_\_\_\_\_

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

\* Plus inerts

18. Analyzed By \_\_\_\_\_ Date \_\_\_\_\_

19. Does this lot require additional testing? \_\_\_ NO \_\_\_ YES - attach page 2

20. SQCU Review/Release \_\_\_\_\_ Date \_\_\_\_\_

MANDATORY FORM

User must assure that this revision of the form is current prior to use. Completed forms become permanent records subject to the record retention policy.



# NITROGEN N.F.

Form Number: 2A-ALL-QUA-0003-F  
 Revision: 0  
 Effective Date: 03/29/06  
 Page: 1/1

**CERTIFICATE OF ANALYSIS**  
**Air Liquide Large Industries U.S. LP - Houston, TX 77056**  
 PRODUCED BY AIR LIQUEFACTION

1. Location *Street Address 1* \_\_\_\_\_  
*Street Address 2* \_\_\_\_\_  
*City, State Zip* \_\_\_\_\_
2. Carrier \_\_\_\_\_
3. Lot Number \_\_\_\_\_
4. Trailer No. \_\_\_\_\_

### PRE-FILL REPORT

### FILL REPORT

5. Residual Assay (≤10 ppm O <sub>2</sub> )  _____ ppm  _____ Initial	6. Odor Detected  Yes No  _____  _____ Initial
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7. Trailer Loaded with appropriate product per appropriate loading procedure by:  Signature _____  Date _____
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### ANALYSIS REPORT

Test Required	Method of Analysis	Specification	Results
ASSAY AND IDENTIFICATION	8. PARAMAGNETIC <input type="checkbox"/>	99.998% N <sub>2</sub> Minimum*	10. _____ %
	MICROFUEL CELL <input type="checkbox"/>	10 ppm O <sub>2</sub> Maximum	11. _____ ppm
	ELECTROCHEMICAL CELL <input type="checkbox"/>		
CARBON MONOXIDE	9. Analyzer Tag Number	10 ppm CO Maximum	14. _____ ppm
	12. DETECTOR TUBE <input type="checkbox"/>	Expiration Date of Tube	15. _____
	INFRARED ANALYZER: <input type="checkbox"/>		
13. Analyzer Tag Number	Lot Number of Tube	16. _____	
ODOR	Organoleptic (Nasal)	None	17. _____

N.F. applies only when used in a medical application or by medical customers properly registered with the FDA.  
 \* Plus inerts

18. Analyzed By \_\_\_\_\_ Date \_\_\_\_\_

19. Does this lot require additional testing? NO YES – attach page 2

20. SQU Review/Release \_\_\_\_\_ Date \_\_\_\_\_

#### MANDATORY FORM

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**NITROGEN**  
 nitrogen gas

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:11853-023
<b>Route of Administration</b>	RESPIRATORY (INHALATION)		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NITROGEN</b> (UNII: N762921K75) (NITROGEN - UNII:N762921K75)	NITROGEN	99 L in 100 L

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:11853-023-60	25000 L in 1 TANK; Type 0: Not a Combination Product	01/01/1960	
2	NDC:11853-023-61	50000 L in 1 TANK; Type 0: Not a Combination Product	01/01/1960	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA205738	01/01/1960	

**Labeler** - Air Liquide Large Industries U.S. LP (180015062)

**Registrant** - Air Liquide Large Industries U.S. LP (180015062)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Air Liquide Large Industries U.S. LP		791294122	manufacture(11853-023)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Air Liquide Large Industries U.S. LP		832290014	manufacture(11853-023)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Air Liquide Large Industries U.S. LP		117158467	manufacture(11853-023)