



# Scientific Documentation

A1337, Arginine Hydrochloride, USP

Not appropriate for regulatory submission.  
Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or  
contact Tech Services for the most up-to-date  
information contained in this information  
package.

**Spectrum Chemical Mfg Corp**

769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300

Ver4.01 19.April.2016



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to be "Alan Wang", written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA  
Senior Manager, Global Supplier Quality Assurance  
[qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

**A1337**, Arginine Hydrochloride, USP

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CHEMICAL MFG CORP



## Specification for Arginine Hydrochloride, USP (A1337)

Item Number	A1337
Item	Arginine Hydrochloride, USP
CAS Number	1119-34-2
Molecular Formula	$C_6H_{14}N_4O_2.HCl$
Molecular Weight	210.66
MDL Number	
Synonyms	L-2-Amino-5-guanidinovaleric Acid Monohydrochloride; L-Arginine Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5 - 101.5 %	
SPECIFIC ROTATION	+21.4 to+23.6	
CHLORIDE CONTENT	16.5 - 17.1 %	
CHROMATOGRAPHIC PURITY		TO PASS TEST
LOSS ON DRYING		0.2 %
RESIDUE ON IGNITION		0.1 %
SULFATE		0.03 %
HEAVY METALS		0.002 %
RESIDUAL SOLVENTS		TO PASS TEST
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		

### *Spectrum Chemical Mfg Corp*

**Corporate Headquarters:**  
769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**  
14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000

## SAFETY DATA SHEET

Preparation Date: 01/20/2015

Revision Date: 1/20/2015

Revision Number: G1

Product identifier

**Product code:** A1337  
**Product Name:** ARGININE HYDROCHLORIDE, USP

Other means of identification

**Synonyms:** Arginine monohydrochloride; Arginine, hydrochloride, L-;  
L-Arginine, monohydrochloride; L-Arginine, hydrochloride (1:1);  
L-(+)-Arginine monohydrochloride  
Argamine; Argivene; Detoxargin; Levargin; Minophagen A

**CAS #:** 1119-34-2  
**RTECS #** CF1995500  
**Cl#:** Not available

Recommended use of the chemical and restrictions on use

**Recommended use:** No information available.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemicals and Laboratory Products, Inc.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

**Other hazards**  
Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
L-Arginine Monohydrochloride 1119-34-2	1119-34-2	100	*

### 4. FIRST AID MEASURES

**First aid measures**

**General Advice:**

Poison information centres in each State capital city can provide additional assistance for scheduled poisons (13 1126)

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:**

Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

**Inhalation:**

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:**

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

**Most important symptoms and effects, both acute and delayed**

**Symptoms**

Health injuries are not known or expected under normal use. May cause eye/skin irritation.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:**

Treat symptomatically

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media**

**Suitable Extinguishing Media:**

Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray. Alcohol-resistant foam.

**Unsuitable Extinguishing Media:**

No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:**

Carbon oxides, Nitrogen oxides, Hydrogen chloride gas

**Specific hazards:**

May be combustible at high temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

## Special Protective Actions for Firefighters

**Specific Methods:** No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice:**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Sensitive to light. Store in light-resistant containers.

#### **Incompatible Materials:**

Strong oxidizing agents.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
L-Arginine Monohydrochloride - 1119-34-2	None	None	None	None

## Canada

Components	Alberta	British Columbia	Ontario	Quebec
L-Arginine Monohydrochloride - 1119-34-2	None	None	None	None

## Australia and Mexico

Components	Australia	Mexico
L-Arginine Monohydrochloride 1119-34-2	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

- Eye protection:** Goggles. Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- Respiratory protection:** Effective dust mask. Wear respirator with dust filter..
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES



## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid.	<b>Appearance:</b> Crystalline. Crystalline powder. Powder.	<b>Color:</b> White.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available	<b>Formula:</b> C6H14N4O2•HCl
<b>Molecular/Formula weight:</b> 210.66	<b>Flash point (°C):</b> No data available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Lower Explosion Limit (%):</b> No information available	<b>Upper Explosion Limit (%):</b> No information available
<b>Autoignition Temperature (°C/°F):</b> No information available	<b>pH:</b> 5.7 (200 g/l) at 20 deg. C	<b>Melting point/range(°C/°F):</b> 219°-230°C/426°-446°F
<b>Boiling point/range(°C/°F):</b> No information available	<b>Decomposition temperature(°C/°F):</b> No information available	<b>Specific gravity:</b> No information available
<b>Density (g/cm3):</b> 0.83	<b>Bulk density:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Completely soluble in water	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

#### **Stability:**

Stable at normal conditions. Sensitive to light. Exposure to light accelerates decomposition.

#### **Possibility of Hazardous Reactions:**

Hazardous polymerization does not occur

#### **Conditions to avoid:**

Heat. Exposure to light. Incompatible materials. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

#### **Incompatible Materials:**

Strong oxidizing agents.

#### **Hazardous decomposition products:**

Carbon oxides. Hydrogen chloride gas. Nitrogen oxides (NOx).

### Other Information

#### **Corrosivity:**

No information available

#### **Special Remarks on Corrosivity:**

No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Product code:** A1337

**Product name:** ARGININE  
HYDROCHLORIDE, USP

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**Principal Routes of Exposure:**  
Eyes. Ingestion. Inhalation. Skin.

**Acute Toxicity**

**Component Information**

*L-Arginine Monohydrochloride - 1119-34-2*

- LD50/oral/rat** = 12000 mg/kg
- LD50/oral/mouse** = No information available
- LD50/dermal/rabbit** = No information available
- LD50/dermal/rat** = No information available
- LC50/inhalation/rat** = No information available
- LC50/inhalation/mouse** = No information available
- Other LD50 or LC50 information** = No information available

**Product Information**

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 12000mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = No information available

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal** = No information available

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor** = No information available  
**VALUE - Gas** = No information available  
**VALUE - Dust/Mist** = No information available

**Symptoms**

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause irritation of respiratory tract.  
**Ingestion** Health injuries are not known or expected under normal use  
Note: The Registry of Toxic Effects of Chemical Substances (RTECS) states that administration by intravenous route (3900 mg/kg/30M continuous) can affect the heart, brain (degenerative changes), and cause metabolic acidosis

**Aspiration hazard** No information available

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity Sensitization:** No information available  
No information available

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
L-Arginine Monohydrochloride	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available  
**Developmental Effects:** No information available  
**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available  
**STOT - repeated exposure** No information available  
**Target Organs:** No information available

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available

**Mobility:** No information available

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Waste from residues / unused products:**

Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
L-Arginine Monohydrochloride	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	Not applicable
<b>Packing Group:</b>	None
<b>ERG No:</b>	No information available
<b>Marine Pollutant</b>	No data available
<b>DOT RQ (lbs):</b>	No information available

### TDG (Canada)

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Description:</b>	No information available

### ADR

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Classification Code:</b>	No information available
<b>Description:</b>	No information available
<b>CEFIC Tremcard No:</b>	No information available

### IMO / IMDG

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Description:</b>	No information available
<b>IMDG Page:</b>	No information available
<b>Marine Pollutant</b>	No information available
<b>MFAG:</b>	No information available
<b>Maximum Quantity:</b>	No information available

### RID

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Classification Code:</b>	No information available
<b>Description:</b>	No information available

### ICAO

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available

**14. TRANSPORT INFORMATION**

**Packing Group:** No information available  
**Description:** No information available

**IATA**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Description:** No information available

**15. REGULATORY INFORMATION****International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>L-Arginine Monohydrochloride</i>	Present	Present KE-01904	Present	Present (2)-1307 (1)-215	Present [21125]	Present	Present 214-275-1

**U.S. Regulations****California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>L-Arginine Monohydrochloride</i>	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting <i>de minimis</i>
<i>L-Arginine Monohydrochloride</i>	None	None	None	None	None

**U.S. TSCA**

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>L-Arginine Monohydrochloride</i>	Not Applicable	Not Applicable

**Canada****WHMIS hazard class:**

Non-controlled

**L-Arginine Monohydrochloride**

Uncontrolled product according to WHMIS classification criteria

**L-Arginine Monohydrochloride****Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

**Inventory**

Components	Canada (DSL)	Canada (NDSL)
L-Arginine Monohydrochloride	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
L-Arginine Monohydrochloride	Not listed	Not listed

**EU Classification****R-phrase(s)**

not determined  
none

**S -phrase(s)**

none

Components	Classification	Concentration Limits:	Safety Phrases
L-Arginine Monohydrochloride		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

**Indication of danger:**

None.  
Not dangerous

**16. OTHER INFORMATION**

**16. OTHER INFORMATION**

<b>NFPA</b>	<b>HMIS</b>	<b>Personal Protective Equipment</b>
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Health Hazard	1
Fire Hazard	1
Reactivity	0



**Preparation Date:** 01/20/2015  
**Revision Date:** 1/20/2015  
**Prepared by:** Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



## Manufacturer

Product Covered: A1337, Arginine Hydrochloride, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

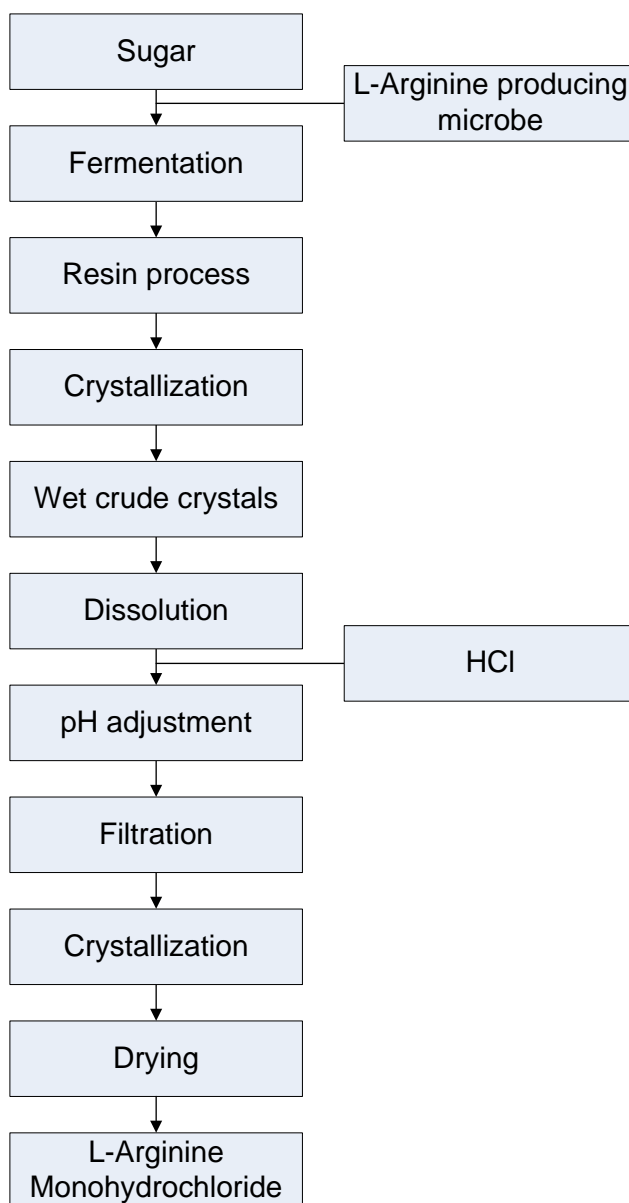
Alan Wang, MSQA, ASQ CQA  
Senior Manager, Global Supplier Quality Assurance  
[qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

19.Apr.2016



## Manufacturing Process Flowchart

### Arginine Hydrochloride, USP - A1337



### ***Spectrum Chemical Mfg Corp***

***Corporate Headquarters:***

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

***West Coast Facility:***

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000

# Certificate of Registration



# Intertek

This is to certify that the quality management system of

## Spectrum Chemicals and Laboratory Products, Inc

**Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA**

*Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA*

*755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA*

*769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA*

*7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA*

has been assessed and registered by Intertek as conforming to the requirements of

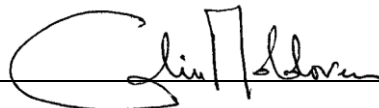
## ISO 9001:2008

The quality management system is applicable to

**California and New Jersey sites:** The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

**Arizona site:** Supporting Spectrum's two manufacturing facilities by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01  
Initial Certification Date: 27 December 1994  
Certificate Issue Date: 29 January 2016  
Certificate Expiry Date: 14 September 2018



*Calin Moldovean, President*  
Intertek Testing Services NA, Inc.  
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 9001-2008-ANAB-EN-LT-L-26.jun.15

# Certificate of Registration

# Intertek

This is to certify that the quality management system of

## Spectrum China Ltd.

**Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China**

has been assessed and registered by Intertek as conforming to the requirements of

## ISO 9001: 2008

The quality management system is applicable to:

*Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.*

Organization Code: 77762704-8  
Certificate Number: 111310001-01  
Certificate Issue Date: 17 November 2015  
Certificate Expiry Date: 14 September 2018



014

A handwritten signature in black ink, appearing to read "Calin Moldovean".

Authorised Signature: Calin Moldovean – President, Business Assurance  
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom  
Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.  
The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.



March 28, 2016

**Certificate of cGMP**

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum -Shanghai, China:	<u>3006174778</u>

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

A handwritten signature in cursive script that reads "Michelle Weston".

Michelle Weston  
Quality Assurance Specialist



April 13, 2016

**Certificate of cGMP**

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
A1337	Arginine Hydrochloride, USP

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824  
Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

Michelle Weston  
Quality Assurance Specialist



April 15, 2016

Re: Arginine Hydrochloride, USP-A1337

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Arginine Hydrochloride, USP-A1337

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature



April 15, 2016

Re: Arginine Hydrochloride, USP-A1337

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Dairy (Milk and Milk derivatives), Starch, Artificial Flavors, Artificial Colors, Eggs and Egg products, Fish and Shellfish products, Tree Nuts, Wheat and Wheat products, Peanut and peanut products, Mustard, Yeast, Seeds, Soybean and soybean products, Cereals containing Gluten, Celery, Preservatives, Sulfites and Coloring agents, Lupin, Mollusk, Grains, Corn, Animal Derivatives, Celery, and Sesame Seed).

Arginine Hydrochloride, USP-A1337

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature



April 15, 2016

Re: Arginine Hydrochloride, USP-A1337

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production. There is no possibility for this product to be contaminated with Aflatoxins during the manufacturing processes.

Arginine Hydrochloride, USP-A1337

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature



## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

**USE CARE:** This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN**

**CAUTION:** For manufacturing, processing or repackaging. Read and understand the label and Safety Data Sheet (SDS) prior to use.

**Chemical Emergency: (800)424-9300**  
www.SpectrumChemical.com

**C<sub>6</sub>H<sub>14</sub>N<sub>4</sub>O<sub>2</sub>•HCl**—F.W. 210.66

Assay (Dried Basis).....	98.5-101.5%
Specific Rotation.....	+21.4° to +23.6°
Chloride Content.....	16.5-17.1%
Chromatographic Purity.....	To pass test

**MAXIMUM LIMITS**

Loss on Drying.....	0.2%
Residue on Ignition.....	0.1%
Sulfate.....	0.03%
Heavy Metals.....	0.002%
Residual Solvents.....	To pass test

**WARNING:** This product contains a chemical known to the State of California to cause cancer.

**WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

G 7/E1GHS    A    **Lot No. 062233**

**SPECTRUM CHEMICAL MFG. CORP.**      **Gardena, CA 90248 • New Brunswick, NJ 08901**

- |   |  |   |
|---|--|---|
| <b>A</b> Bar Code   | <b>F</b> Size/Quantity   | <b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel |
| <b>B</b> GHS Hazard Pictograms                              | <b>G</b> Chemical Abstracts Service (CAS) Registry Number      | <b>L</b> Expiration Information   |
| <b>C</b> Warning, Safety Data and Precautionary Information | <b>H</b> Caution Information                                   | <b>M</b> Lot Number   |
| <b>D</b> Product Catalog Number                             | <b>I</b> DOT Shipping Information                              | <b>N</b> Kosher Certified by Kosher Supervision of America (KSA).             |
| <b>E</b> Item Name, Form, Grade                             | <b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number |   |
| <b>O</b> Storage Color Band                                 |  |   |

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

### Spectrum Chemical Mfg Corp

**Corporate Headquarters:**

769 Jersey Ave.  
New Brunswick, NJ 08901

732.214.1300

**West Coast Facility:**

14422 S. San Pedro St.  
Gardena, CA 90248

310.516.8000

Item Number	A1337	Lot Number	1EJ0325
Item	Arginine Hydrochloride, USP		
CAS Number	1119-34-2		
Molecular Formula	$C_6H_{14}N_4O_2 \cdot HCl$	Molecular Weight	210.66

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.5 - 101.5 %		99.8 %
SPECIFIC ROTATION	+21.4 to+23.6		+22.6
CHLORIDE CONTENT	16.5 - 17.1 %		16.8 %
CHROMATOGRAPHIC PURITY		TO PASS TEST	PASSES TEST
LOSS ON DRYING		0.2 %	0.00 %
RESIDUE ON IGNITION		0.1 %	0.00 %
SULFATE		0.03 %	<0.02 %
HEAVY METALS		0.002 %	<0.0005 %
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			09-DEC-2017
MANUFACTURE DATE			09-DEC-2014
APPEARANCE			WHITE CRYSTALLINE POWDER

Spectrum Chemical Mfg Corp  
 14422 South San Pedro Street  
 Gardena 90248 CA

Certificate of Analysis Results Certified By:



Adan Hernandez  
 Quality Control Manager  
 Spectrum Chemicals & Laboratory Products



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Item Number	A1337	Lot Number	2EI0027
Item	Arginine Hydrochloride, USP		
CAS Number	1119-34-2		
Molecular Formula	$C_6H_{14}N_4O_2 \cdot HCl$	Molecular Weight	210.66

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.5 - 101.5 %		100.1 %
SPECIFIC ROTATION	+21.4 to+23.6		+22.60
CHLORIDE CONTENT	16.5 - 17.1 %		16.80 %
CHROMATOGRAPHIC PURITY		TO PASS TEST	PASSES TEST
LOSS ON DRYING		0.2 %	0.01 %
RESIDUE ON IGNITION		0.1 %	0.04 %
SULFATE		0.03 %	<0.02 %
HEAVY METALS		0.002 %	<0.0005 %
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			01-JUL-2017
DATE OF MANUFACTURE			01-JUL-2014
APPEARANCE			WHITE CRYSTALLINE POWDER

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:




Mulbah F. Dwanah  
Laboratory Supervisor  
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

January 26, 2016

**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example:** ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example:** 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,



Michael Dang  
Manager, GMP Compliance



## Stability – Shelf Life Guidance

Product Covered: A1337, Arginine Hydrochloride, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, A1337, Arginine Hydrochloride, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez  
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters  
769 Jersey Avenue  
New Brunswick, NJ 08901-3605