



Scientific Documentation

L1142, Lysine Hydrochloride, Granular, USP

Not appropriate for regulatory submission.
Please visit 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

Ver4.04 18.April.2019



Dear Customer,

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

Spectrum has been proudly serving the 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 blue ink, appearing to read "Michael Dang", with a stylized flourish at the end.

Michael Dang
Director, Quality Systems & GMP Compliance
mdang@spectrumchemical.com

18.April.2019

L1142, Lysine Hydrochloride, Granular, USP

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Specification for Lysine Hydrochloride, Granular, USP (L1142)

Item Number	L1142
Item	Lysine Hydrochloride, Granular, USP
CAS Number	657-27-2
Molecular Formula	$C_6H_{14}N_2O_2.HCl$
Molecular Weight	182.65
MDL Number	
Synonyms	2,6-Diaminohexanoic Acid Hydrochloride ; L-Lysine Monohydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	101.5%
SPECIFIC ROTATION $[\alpha]_D$	+20.4° to +21.4°	
CHLORIDE CONTENT	19.0	19.6%
RELATED COMPOUNDS:	.	
INDIVIDUAL IMPURITIES		0.5 %
TOTAL IMPURITIES		2.0 %
LOSS ON DRYING		0.4%
RESIDUE ON IGNITION		0.1%
SULFATE		0.03%
IRON		30 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

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: 10/29/2014

Revision Date: 10/29/2014

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: L1142
Product Name: LYSINE HYDROCHLORIDE, GRANULAR, USP

Other means of identification

Synonyms: Lysine hydrochloride
Lyamine
L-Lysine hydrochloride
Lysine monohydrochloride
CAS #: 657-27-2
RTECS # OL5650000
CI#: 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
Lysine Monohydrochloride 657-27-2	657-27-2	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

May cause eye/skin irritation. May cause nausea and vomiting. Dyspnea (Difficulty breathing and shortness of breath).

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 (CO₂). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products:

Carbon monoxide; Carbon dioxide; nitrogen oxides; hydrogen chloride gas

Specific hazards:

May be combustible at high temperatures

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: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental precautions No information available.

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. All equipment used when handling the product must be grounded. 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.

Incompatible Materials:

Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

U.S Occupational Exposure Limits: Not determined

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Lysine Monohydrochloride - 657-27-2	None	None	None	None

Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
Lysine Monohydrochloride - 657-27-2	None	None	None	None

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Lysine Monohydrochloride 657-27-2	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:** Safety glasses. Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- Respiratory protection:** Effective dust mask.
- 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

Physical state: Solid.	Appearance: Powder. Crystalline powder. Granular.	Color: White. Off-white.
Odor: Odorless.	Taste No information available	Formula: C6-H14-N2-O2.HCl
Molecular/Formula weight: 182.65	Flash point (°C): No data available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Lower Explosion Limit (%): No information available	Upper Explosion Limit (%): No information available
Autoignition Temperature (°C/°F): No information available	pH: No information available	Melting point/range(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available	Specific gravity: No information available
Density (g/cm3): No information available	Bulk density: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Water	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable at normal conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. 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 monoxide. Carbon dioxide. Nitrogen oxides (NOx). Hydrogen chloride gas.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product code: L1142

Product name: LYSINE
HYDROCHLORIDE, GRANULAR, USP

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Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Lysine Monohydrochloride - 657-27-2

LD50/oral/rat = 10000 mg/kg (RTECS)
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 = 10000mg/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 Low hazard. Ingestion may cause nausea, vomiting. May affect respiration (dyspnea - difficulty breathing and shortness of breath). May affect behavior/central nervous system (ataxia).

Aspiration hazard No information available

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

Chronic Toxicity No information available

Sensitization: No information available

Mutagenic Effects: No information available

Carcinogenic effects: No information available.

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Lysine 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
Lysine Monohydrochloride	None	None	None	None

14. TRANSPORT INFORMATION

14. TRANSPORT INFORMATION

DOT

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

TDG (Canada)

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

ADR

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

IMO / IMDG

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
IMDG Page:	No information available
Marine Pollutant	No information available
MFAG:	No information available
Maximum Quantity:	No information available

RID

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
Classification Code:	No information available
Description:	No information available

ICAO

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

14. TRANSPORT INFORMATION

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>Lysine Monohydrochloride</i>	Present	Present KE-22666	Present	Present (9)-1633 (1)-215	Present	Present	Present 211-519-9

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>Lysine 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>Lysine 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>Lysine Monohydrochloride</i>	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

Non-controlled

Lysine Monohydrochloride

Uncontrolled product according to WHMIS classification criteria

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.

Product code: L1142

Product name: LYSINE
HYDROCHLORIDE, GRANULAR, USP

Lysine Monohydrochloride

Inventory

Components	Canada (DSL)	Canada (NDSL)
Lysine Monohydrochloride	Present	Not Listed

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

EU Classification

R-phrases(s)

not determined

S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Lysine Monohydrochloride		No information	

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

Indication of danger:

Not dangerous

16. OTHER INFORMATION

16. OTHER INFORMATION**NFPA****HMIS****Personal Protective Equipment**

Health Hazard	1
Fire Hazard	1
Reactivity	0

**See Section 8.**

Preparation Date: 10/29/2014
Revision Date: 10/29/2014
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 Material Safety Data Sheet



Manufacturer

Product Covered: L1142, Lysine Hydrochloride, Granular, 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,

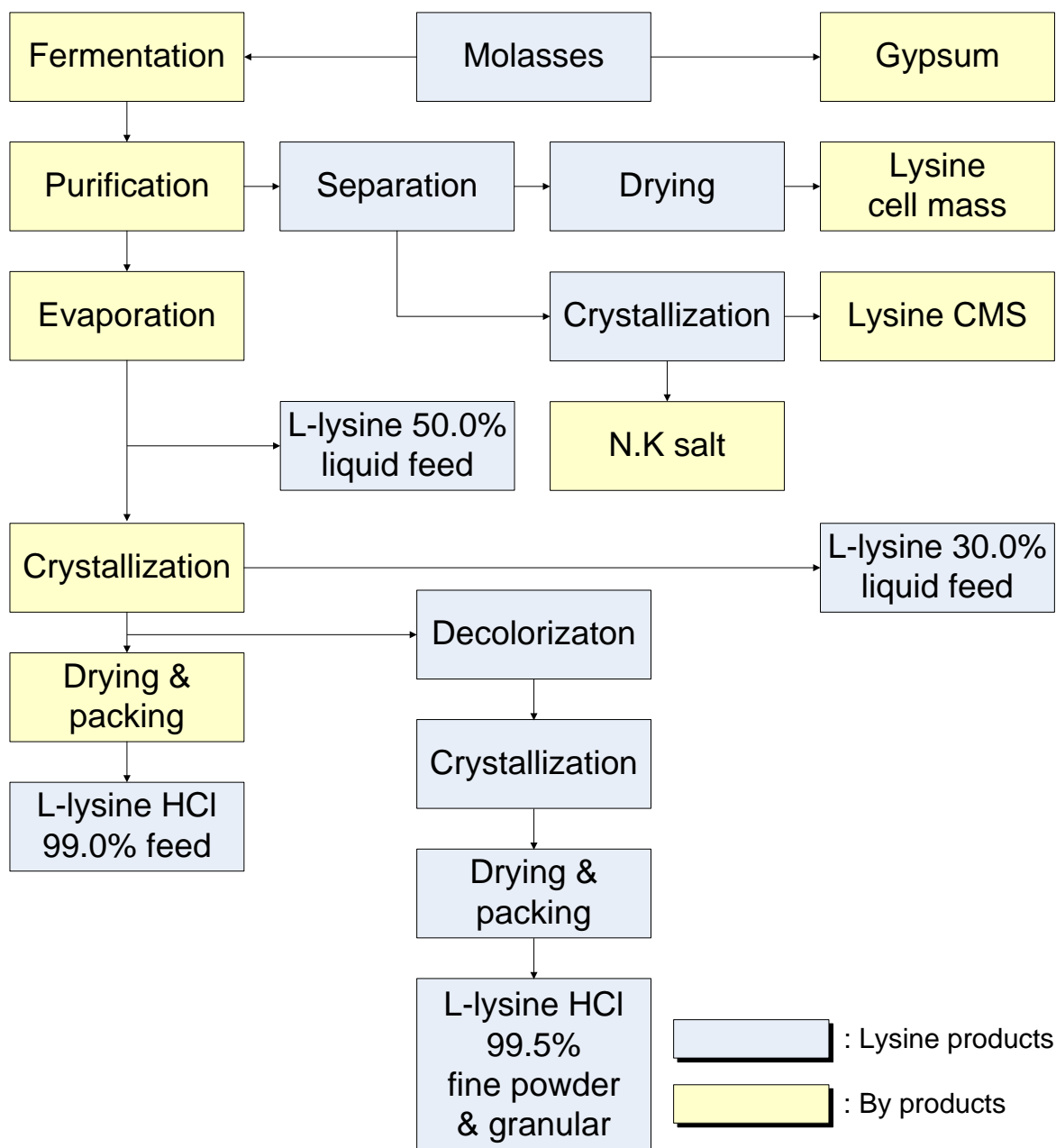
A handwritten signature in blue ink, appearing to read "Michael Dang", with a long horizontal flourish extending to the right.

Michael Dang
Director, Quality Systems & GMP
Compliance
mdang@spectrumchemical.com

18.April.2019

Manufacturing Process Flowchart

Lysine Hydrochloride, Granular, USP - L1142



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

This is to certify that the management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street,
Gardena, California, 90248, United States

Additional Site: 13915 South Main Street,
Los Angeles, California, 90061, United States

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

Certificate Number:

94-316m

Initial Certification Date:

27 December 1994

Date of Certification Decision:

22 January 2019

Issuing Date:

22 January 2019

Valid Until:

28 January 2022



Intertek

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

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.,
900 Chelmsford Street,
Lowell, MA 01851.
USA.



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations covered by the management system of:

Spectrum Chemicals and Laboratory Products, Inc.

This appendix is linked to the Main Certificate # 94-316m and cannot be shown nor reproduced without it.

Spectrum Chemicals and Laboratory Products, Inc.

769 Jersey Avenue,
New Brunswick, New Jersey, 08901, United States

755 Jersey Avenue,
New Brunswick, New Jersey, 08901, United States

777 Jersey Avenue,
New Brunswick, New Jersey, 08901, United States

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

Spectrum Chemicals and Laboratory Products, Inc.

7400 N. Oracle, Suite 201,
Tucson, Arizona, 85704, United States

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.



管理体系认证 注册证书

兹证明，以下组织：

斯百全化学(上海) 有限公司

注册地址：上海市松江区申港路3802号41幢

经营地址：上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售。

统一社会信用代码：

91310000777627048K

证书编号：

111310001

首次认证日期：

2015年11月17日

认证决定日期：

2018年10月15日

签发日期：

2018年10月15日

有效期至：

2021年11月10日



014

Calin Moldovean

President, Business Assurance

Intertek Certification Limited, 10A Victory
Park, Victory Road, Derby DE24 8ZF, United
Kingdom

Intertek Certification Limited
是 UKAS 认可的认证机构，
注册号为 014



对于此证书的签署，Intertek仅对获证组织承担认证协议所规定的义务，而不对其他组织承担任何义务。此证书的有效性基于获证组织能够依照Intertek的体系认证要求使其体系得到保持。可通过电子邮件certificate.validation@intertek.com或用智能手机扫描该代码对证书有效性进行确认。此证书的所有权归属为Intertek，在必要时证书持有者应按要求归还证书。

获证组织必须定期接受监督审核并经审核合格方可保持证书年度有效。证书信息可在国家认监委官网<http://www.cnca.gov.cn>查询。



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Spectrum China Ltd.

Registered Address: Building 41, No.3802, Shengang Road,
Songjiang District, Shanghai, China

Business Address: Building A20, No.3802, Shengang Road,
Songjiang District, Shanghai, China

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals.

Unified Social Credit Identifier:

91310000777627048K

Certificate Number:

111310001

Initial Certification Date:

17 November 2015

Date of Certification Decision:

15 October 2018

Issuing Date:

15 October 2018

Valid Until:

10 November 2021



014

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.



January 15, 2018

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

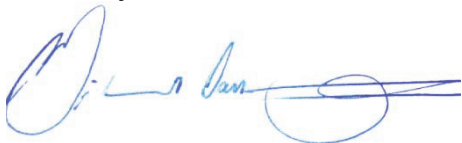
Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

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

Spectrum Gardena, California:	<u>2020632</u>
Spectrum New Brunswick, New Jersey:	<u>2246824</u>

Thank you for your interest in Spectrum products. Please feel free to contact me at 310-516-8000, extension 5610 or via email at mdang@spectrumchemical.com if I may be of further assistance.

Sincerely,



Michael Dang
Director, Quality Systems & GMP Compliance

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

April 18, 2019

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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
L1142	Lysine Hydrochloride, Granular, 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: 03006174778

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,



Oralia Chavez
Quality Assurance Specialist



April 17, 2019

Re: Lysine Hydrochloride, Granular, USP- L1142

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 Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Lysine Hydrochloride, Granular, USP- L1142

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.

Sincerely,

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

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



April 17, 2019

Re: Lysine Hydrochloride, Granular, USP- L1142

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 the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Lupin; Tree nuts; Mollusks; Wheat; Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10mg/l expressed as SO₂; Peanuts; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Lysine Hydrochloride, Granular, USP- L1142

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

Sincerely,

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

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Item Number	L1142	Lot Number	1GL0599
Item	Lysine Hydrochloride, Granular, USP		
CAS Number	657-27-2		
Molecular Formula	$C_6H_{14}N_2O_2 \cdot HCl$	Molecular Weight	182.65

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.5	101.5%	99.92 %
SPECIFIC ROTATION $[\alpha]_D$	+20.4° to +21.4°		+20.98°
CHLORIDE CONTENT	19.0	19.6%	19.45 %
RELATED COMPOUNDS	TO PASS TEST		PASSES TEST
LOSS ON DRYING		0.4%	0.20 %
RESIDUE ON IGNITION		0.1%	0.01 %
SULFATE		0.03%	<0.03 %
IRON		30 ppm	<30 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			09-FEB-2020
DATE OF MANUFACTURE			10-FEB-2017
APPEARANCE			WHITE GRANULES
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED

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.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

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.

Exp. Date: 03-31-2025

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

SPECTRUM[®]

L1142 **1 KG**

Lysine Hydrochloride

(2,6-Diaminohexanoic Acid Hydrochloride;
L-Lysine Monohydrochloride)

Granular
U.S.P.
CAS 657-27-2

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

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

C₆H₁₄N₂O₂•HCl **F.W. 182.65**

Assay (Dried Basis) 98.5-101.5%
Specific Rotation, [α]_D²⁰ +20.4° to +21.4°
Chloride Content 19.0-19.6%
Chromatographic Purity To pass test

MAXIMUM LIMITS

Loss on Drying 0.4%
Residue on Ignition 0.1%
Sulfate 0.03%
Iron 0.003%
Heavy Metals 0.0015%
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.

G 8/D10GHS A **Lot No. 062233**

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

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

June 15, 2018

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 928th 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 706th 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 if we may be of further assistance.

Sincerely,



Michael Dang
Director, Quality Systems & GMP Compliance
mdang@spectrumchemical.com



Stability – Shelf Life Guidance

Product Covered: L1142, Lysine Hydrochloride, Granular, USP

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

The product, L1142, Lysine Hydrochloride, Granular, 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 blue ink, appearing to read "Adan R. Hernandez".

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