

Scientific Documentation

Arginine, 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





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Specification for Arginine, USP (A1334)

Item Number	A1334
Item	Arginine, USP
CAS Number	74-79-3
Molecular Formula	$C_6H_{14}N_4O_2$
Molecular Weight	174.20
MDL Number	
Synonyms	L-2-Amino-5-guanidinovaleric Acid

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	101.5 %
SPECIFIC ROTATION [a] _D	+26.3° to +27.7°	
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.3 %
CHLORIDE (CI)		0.05 %
SULFATE (SO ₄)		0.03 %
IRON (Fe)		30 ppm
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)		AS REPORTED
LEAD (Pb)		AS REPORTED
ARSENIC (As)		AS REPORTED
MERCURY (Hg)		AS REPORTED
ORGANIC IMPURITIES:	•	
INDIVIDUAL IMPURITIES		0.5 %
TOTAL IMPURITIES		2.0 %
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
CERTIFIED KOSHER		
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		

Test	Specifi	cation
	Min	Max
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	A1334	Lot Number	1ML0181
Item	Arginine, USP	CAS Number	74-79-3
Molecular Formula	$C_6H_{14}N_4O_2$	Molecular Weight	174.20

TECT	SPECIFICATION		DEGLET	
TEST	MIN	MAX	RESULT	
ASSAY (DRIED BASIS)	98.5	101.5 %	99.7 %	
SPECIFIC ROTATION [a] _D	+26.3° to +27.7°		+26.6°	
LOSS ON DRYING		0.5 %	0.2 %	
RESIDUE ON IGNITION		0.3 %	0.0 %	
CHLORIDE (CI)		0.05 %	<0.05 %	
SULFATE (SO ₄)		0.03 %	<0.03 %	
IRON (Fe)		30 ppm	<30 ppm	
ELEMENTAL IMPURITIES:				
CADMIUM (Cd)		AS REPORTED	<1 μg/g	
LEAD (Pb)		AS REPORTED	<3 μg/g	
ARSENIC (As)		AS REPORTED	<1 μg/g	
MERCURY (Hg)		AS REPORTED	<0.1 μg/g	
ORGANIC IMPURITIES:				
INDIVIDUAL IMPURITIES		0.5 %	<0.5 %	
TOTAL IMPURITIES		2.0 %	<2.0 %	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
CERTIFIED KOSHER			CERTIFIED KOSHER	
CERTIFIED HALAL			CERTIFIED HALAL	
EXPIRATION DATE			01-NOV-2025	
DATE OF MANUFACTURE			02-NOV-2023	
APPEARANCE			WHITE POWDER	
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS PRESENT	
MONOGRAPH EDITION			(USP-NF) 2023	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 24-JAN-24 08:40:46

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 24-JAN-24 10:28:47

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.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.





Revision date 29-September-2022

Revision Number 2

1. Identification

Product identifier

Product Name ARGININE, USP

Other means of identification

Product Code(s) A1334

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

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

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

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

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Crystalline powder or

Physical state Solid

Odor No information available

Crystals

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
L-Arginine	74-79-3	100

4. First-aid measures

Description of first aid measures

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Wash skin with soap and water.

Ingestion Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protectionNo special protective equipment required.

Respiratory protectionNo protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Crystalline powder or Crystals

Color White

Odor No information available Odor threshold No information available

Property Values Remarks • Method

no data available None known pН 235 - 244 °C / 455 - 471.2 °F Melting point / freezing point None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure No data available None known Vapor density no data available None known Relative density 1.4 None known Soluble in water None known Water solubility Solubility(ies) Insoluble in diethyl ether None known None known Partition coefficient -4.2 None known **Autoignition temperature** no data available **Decomposition temperature** None known

Kinematic viscosity

no data available

None known

No data available

None known

Other information

Explosive properties
Oxidizing properties
No information available
No information available
No information available

Molecular weight 174.20

VOC Content (%)
Liquid Density
No information available
No information available
No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

No information available

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity No information available. No information available. No information available. No information available.

Reproductive toxicity No information available.

STOT - single exposure STOT - repeated exposure Aspiration hazard No information available. No information available. No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
L-Arginine	-	LC50: =2.8g/L (96h,	-	-
74-79-3		Danio rerio)		

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT not regulated

TDG not regulated

MEX not regulated

not regulated ICAO (air)

not regulated IATA

not regulated **IMDG**

RID not regulated

ADR not regulated

ADN not regulated

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL Complies Complies **EINECS/ELINCS**

ENCS This product complies with ENCS: **IECSC** This product complies with China:

Complies **KECL** Complies **PICCS**

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances **IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 0 Flammability 0 Instability 0

Physical and chemical properties -

HMIS

Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 29-September-2022 Revision Note 29-September-2022 No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet



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	
A1334	Arginine, 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

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

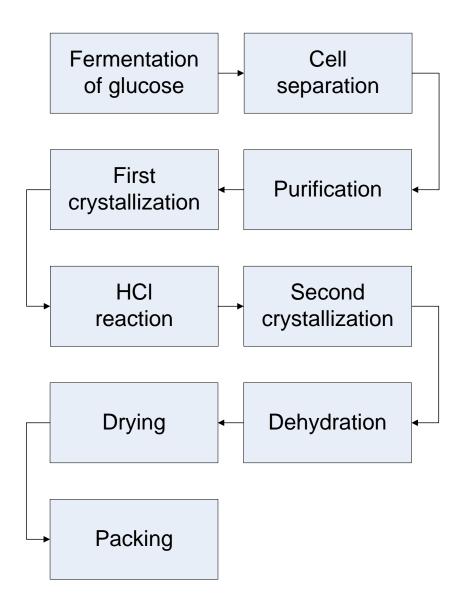
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Arginine, USP - A1334



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



A1334, Arginine, USP

Source Statement

The above mentioned catalog item is manufactured by fermentation of plant derived material (Glucose). No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 24 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Arginine, USP (Cat# A1334)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 3 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 0.1 ppm
Cobalt	Со	2A	Lot specific analysis*
Vanadium	V	2A	Lot specific analysis*
Nickel	Ni	2A	Lot specific analysis*
Thallium	TI	2B	Not tested **
Gold	Au	2B	Not tested **
Palladium	Pd	2B	Not tested **
Iridium	lr	2B	Not tested **
Osmium	Os	2B	Not tested **
Rhodium	Rh	2B	Not tested **
Ruthenium	Ru	2B	Not tested **
Selenium	Se	2B	Not tested **
Silver	Ag	2B	Not tested **
Platinum	Pt	2B	Not tested **
Lithium	Li	3	Not tested **
Antimony	Sb	3	Not tested **
Barium	Ba	3	Not tested **
Molybdenum	Мо	3	Not tested **
Copper	Cu	3	Not tested **
Tin	Sn	3	Not tested **
Chromium	Cr	3	Not tested **

^{*} Refer to CofA for lot specific analysis

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

^{**} Elements indicated as "Not tested" are not intentionally added to the manufacturing process.



Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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



RE: Residual Solvents - Arginine, USP (Cat# A1334)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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PHONE 310.516.8000
FAX 310.516.9843



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. Below you will find a typical label example for this catalog item.

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

A1334 SIZ SY **Arginine**

(L-2-Amino-5-guanidinovaleric Acid)

KSA

USP CAS 74-79-3



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

 $C_6H_{14}N_4O_2$ F.W. 174.20

Assay (Dried Basis) Specific Rotation, $[\alpha]_0^{25}$ +26.3° to +27.7° MAXIMUM LIMITS

Loss on Drying . Residue on Ignition Chloride (CI) Sulfate (SO₄) Iron (Fe) ... Elemental Impurities As reported Organic Impurities To pass test Residual Solvents To pass test

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

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

Lot No. XQ#### G 14/K11GHS

Spectrum Chemical Mfg Corp

769 Jersey Ave.

732.214.1300

New Brunswick, NJ 08901

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

Corporate Headquarters:





The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA

Product Name A1334, Arginine, USP

Brand Spectrum

UKD-ID KSAV3-I6I6H63

D/P/M

Symbol Required KSA

Special Conditions

This certificate expires on **Feb 01, 2025**

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.