

Scientific Documentation AM125, Glycine, USP

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> 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

Ver4.03 12.May.2017



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,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

AM125, Glycine, USP

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Item Number	AM125
Item	Glycine, USP
CAS Number	56-40-6
Molecular Formula	C ₂ H ₅ NO ₂
Molecular Weight	75.07
MDL Number	
Synonyms	Aminoacetic Acid ; Glycocoll

Test	Specif	ication
	Min	Max
ASSAY (NH ₂ CH ₂ COOH)	98.5 - 101.5 %	
LOSS ON DRYING		0.2 %
RESIDUE ON IGNITION		0.1 %
CHLORIDE (Cl)		0.007 %
SULFATES (SO ₄)		0.0065
HEAVY METALS		0.002 %
HYDROLYZABLE SUBSTANCES		TO PASS TEST
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
RESIDUAL SOLVENTS		TO PASS TEST

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000





SAFETY DATA SHEET

Preparation Date: 6/26/2014 Revision Date: 6/26/2014 Revision Number: G1 **IDENTIFICATION** 1. **Product identifier** Product code: AM125 **Product Name:** GLYCINE, USP Other means of identification Synonyms: Aminoacetic acid: 2-Aminoacetic acid; Aciport: Aminoethanoic acid: Glicoamin: Glycocoll; Glycolixir; Glycosthene; Hampshire glycine; Padil; Glycine CAS #: 56-40-6 **RTECS #** MB7600000 CI#: Not available Recommended use of the chemical and restrictions on use **Recommended use:** Buffer. In organic synthesis. Nutrient. Dietary supplement. Uses advised against No information available Spectrum Chemicals and Laboratory Products, Inc. Supplier: 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:** Regina Wachenheim (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

Hazards not otherwise classified (HNOC) Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Glycine	56-40-6	100	*
56-40-6			

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.
	nd effects, both acute and delayed
Symptoms	May cause eye/skin irritation. May cause nausea and vomiting.

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:

Specific hazards:

Carbon monioxide; Carbon dioxide; nitrogen oxides

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:

Special Protective Equipment for Firefighters:

No information available.

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

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	None	None	None	None
Glycine - 56-40-6				

Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
	None	None	None	None
Glycine - 56-40-6				

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Glycine	None	None
56-40-6		

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. 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

Physical state: Solid.

Odor: Odorless.

Molecular/Formula weight: 75.07

Flash Point Tested according to: Closed cup

Autoignition Temperature (°C/°F): No information available

Boiling point/range(°C/°F): No information available

Density (g/cm3): 1.1607

Evaporation rate: No information available

Odor threshold (ppm): No information available

Miscibility: No information available Appearance: Crystalline powder. Crystals.

Taste No information available

Flash point (°C): No data available

Lower Explosion Limit (%): No information available

pH: No information available

Decomposition temperature(°C/°F):SpecificStarts to decompose at 233°C (451.4°F); 1.16-1.2Completely sintered at 280 deg. C.(536deg. F)Bulk density:Vapor pNo information availableNo information

Vapor density: No information available

Partition coefficient (n-octanol/water): -3.21

Solubility: Insoluble in Ethanol Insoluble in Ether Slightly soluble in Acetone Very soluble in water Solubilitiy in Water: 25 g/100 ml @25 deg. C; 39.1 g/100 ml @ 50 deg. C; 54.4 g/100 ml @ 75 deg. C; 67.2 g/100 ml @ 100 deg. C.

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).

Other Information

Color: White.

Formula: C2-H5-N-O2

Flashpoint (°C/°F): >176.67 °C/350 °F

Upper Explosion Limit (%): No information available

Melting point/range(°C/°F): 182 °C/359.6 °F

Specific gravity: 1.16-1.2

Vapor pressure @ 20°C (kPa): No information available

VOC content (g/L): No information available

Viscosity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure: Ingestion. Inhalation.

Acute Toxicity

Component Information

Glycine - 56-40-6

LD50/oral/rat = 7930 mg/kg Oral LD50 Rat LD50/oral/mouse = 4920 mg/kg LD50/dermal/rabbit = No information available LD50/dermal/rat = No information available LC50/inhalation/rat = No information available LC50/inhalation/mouse = No infomation available Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = 7930mg/kg

LD50/oral/mouse = Value - Acute Tox Oral = 4920mg/kg

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 Ingestion	May cause irritation of respiratory tract. Low hazard. Large doses may cause nausea and vomiting. It may also affect behavior (muscle weakness, ataxia).

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:	May affect genetic material

Carcinogenic effects:

No information available.

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

Not regulated No information available No information available

Not applicable

No data available No information available No information available

None

DOT

UN-No:
Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant
ERG No:
DOT RQ (lbs):

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: Proper Shipping Name:	Not Regulated 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:
Proper Shipping Name:
Hazard Class:
Subsidiary Risk:

Not Regulated No information available No information available No information available

14. TRANSPORT INFORMATION

Packing Group:	
Description:	

No information available No information available

ΙΑΤΑ

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.
Glycine	Present T	Present KE- 01153	Present	Present (9)-77	Present	Present	Present 200-272-2

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:
Glycine	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

	Substances and their	Hazardous	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Glycine	None	None	None	None	None

U.S. TSCA

	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Glycine	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

Non-controlled

Glycine

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.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Glycine	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Glycine	Not listed	Not listed

EU Classification

R-phrase(s) not determined

S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Glycine		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 Hazard1Fire Hazard1Reactivity0	
		See Section 8.
Preparation Date: 6/26	/2014	

6/26/2014 Sonia Owen

Preparation Date: Revision Date: Prepared by:

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: AM125, Glycine, 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,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

Certificate of Registration



This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Frc

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 facilitates by: selecting and gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01 Initial Certification Date: 27 December 1994 Certificate Issue Date: Certificate Expiry Date:

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



CERTIFICATION



Intertek Intertek

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 or by scanning the code to the right with a smartphone.

Certificate of Registration



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



014

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 <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone. The annual validity of the certificate a also be checked through the website <u>http://www.cnca.gov.cn</u> of CNCA in China.



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



January 03, 2017

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products 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 follow:

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

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

Sincerely,

Michael Dang Manager, 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



July 14, 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
AM125	Glycine, 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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 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 <u>gualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Order Anny

Oralia Chavez Quality Assurance Specialist



May 4, 2016

Re: Glycine, USP- AM125

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

Glycine, USP- AM125

is BSE/TSE free.

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

Sincerely,

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

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



May 4, 2016

Re: Glycine, USP- AM125

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 (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Tree nuts; Wheat; Peanuts; Soy; Cereals containing Gluten; Sesame Seed).

Glycine, USP- AM125

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

Sincerely,

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

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

Spectrum®

Certificate Of Analysis

Item Number	AM125	Lot Number	2GB0203
Item	Glycine, USP		
CAS Number	56-40-6		
Molecular Formula	C ₂ H ₅ NO ₂	Molecular Weight	75.07

Test	Specification		Result
	min	max	
ASSAY (NH ₂ CH ₂ COOH)	98.5 - 101.5 %		99.1 %
LOSS ON DRYING		0.2 %	0.09 %
RESIDUE ON IGNITION		0.1 %	0.029 %
CHLORIDE (CI)		0.007 %	<0.007 %
SULFATES (SO ₄)		0.0065 %	<0.0065 %
HEAVY METALS		0.002 %	<0.001 %
HYDROLYZABLE SUBSTANCES		TO PASS TEST	PASSES TEST
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			26-SEP-2019
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE CRYSTALLINE POWDER
DATE OF MANUFACTURE			26-SEP-2016

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

Ibad Tirmizi Director of Quality Spectrum Chemical Mfg. Corp.

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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



BLUE: Health Hazard WHITE: Corrosive

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 	AM125 AM125 Calycine (Aminoacetic Acid; Glycocoll) U.S.P. CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.	Assay (Dried Basis) 98.5-101.5% MAXIMUM LIMITS 0.29 Residue After Ignition 0.1% Chloride (Cl) 0.007% Sulfate (SO ₄) 0.0065% Heavy Metals 0.002% Hydrolyzable Substances To pass test Residual Solvents To pass test WARNING: This product contains a chemical know to the State of California to cause cancer. WARNING: This product contains a chemical know to the State of California to cause birth defects of other reproductive harm.
SPECTRUM CHEMICAL I	Chemical Emergency: (800)424-9300 www.SpectrumChemical.com MFG. CORP. Gardena, CA 90	G 9/D6GHS A OLOT NO. 06223 248 • New Brunswick, NJ 08901

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.

Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000



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 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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: AM125, Glycine, USP

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

The product, AM125, Glycine, 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

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



شهادة حلال IFANCA HALAL PRODUCT CERTIFICATE

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America (IFANCA[®]). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: January 26, 2017 Document #: 11205.11206.II170376

		ducts, Inc. 769- Jersey Avenue, New Br ducts, Inc. 769-Jersey Ave, New Brunsv	-	A
Product Name		Product Code	Halal-ID	Product Certificate #
Glycine, USP		AM125	C15489	HC-17SPNB64
Mahamma Hum Chaudry Muhammad Munir Chaudry, Ph.D. President	NUTRITION COLUCIOF AMO	This certificate is valid until August 3		at that time. Page 1 of 1