

# **Scientific Documentation**

# **DL-Methionine, FCC**

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





# **Table of Contents**

Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Manufacturing Process Flowchart Technical Statements General Label Information – Sample Label



# **Specification for DL-Methionine, FCC (ME126)**

Item Number	ME126
Item	DL-Methionine, FCC
CAS Number	59-51-8
Molecular Formula	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S
Molecular Weight	149.21
MDL Number	
Synonyms	DL-2-Amino-4-(methylthio)butyric Acid

Test	Specification	
	Min	Max
ASSAY (C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S; DRIED BASIS)	98.5	101.5 %
LEAD (Pb)		5 mg/kg
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
IDENTIFICATION		PASSES TEST
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		

#### 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



# **Certificate Of Analysis**

Item Number	ME126	Lot Number	1JA0173
Item	DL-Methionine, FCC	CAS Number	59-51-8
Molecular Formula	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S	Molecular Weight	149.21

TEST	SPECIFICATION		
IESI	MIN	MAX	RESULT
ASSAY (C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S; DRIED BASIS)	98.5	101.5 %	100.1 %
LEAD (Pb)		5 mg/kg	<0.3 mg/kg
LOSS ON DRYING		0.5 %	0.00 %
RESIDUE ON IGNITION		0.1 %	0.06 %
IDENTIFICATION		PASSES TEST	PASSES TEST
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			28-MAY-2024
DATE OF MANUFACTURE			29-MAY-2018
APPEARANCE			WHITE CRYSTALS

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 10-JAN-20 14:00:09

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



Certificate of Analysis Results Approved By:

HBERMUDEZ Hernan Bermudez 10-JAN-20 14:01:29

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.

# SAFETY DATA SHEET

Revision date 19-September-2022

1. Identification	
Product identifier	
Product Name	DL-METHIONINE, FCC
Other means of identification	
Product Code(s)	ME126
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 Powder or Plates

Physical state Solid

Odor No information available



Revision Number 2

Other information No information available.

# 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
DL-Methionine	59-51-8	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 effe	cts, both acute and delayed
<u>Most important symptoms and effe</u> Symptoms	cts, both acute and delayed No information available.
Symptoms	

# 5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. 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.	
Explosion data Sensitivity to mechanical impac	at 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

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 protection	No special protective equipment required.
Respiratory protection	No 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	Powder or Plates
Color	White
Odor	No information available
Odor threshold	No information available

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Bulk density No information available			
	Bulk density	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 materials	None 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	The environmental impact of this product has not been fully investigated.
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
ICAO (air)	not regulated
IATA	not regulated
IMDG	not regulated
<u>RID</u>	not regulated

ADR	not regulated

ADN not regulated

#### 15. Regulatory information

#### International Inventories

**TSCA** 

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical
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

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#### 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 TŴĂ 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	19-September-2022
Revision Note	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** 

# spectrum

#### 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
ME126	DL-Methionine, FCC

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:2020632Spectrum-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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

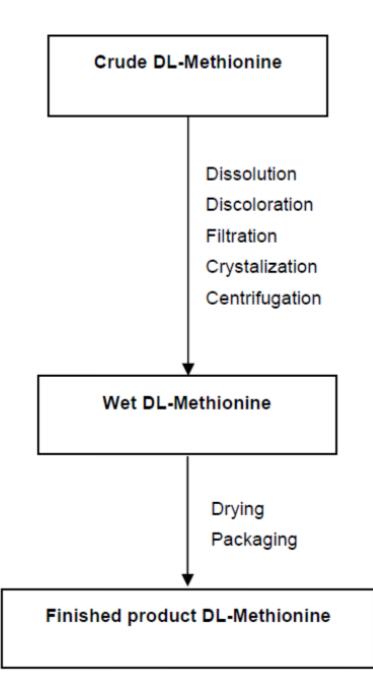
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



# **Manufacturing Process Flowchart**

DL-Methionine, FCC (Cat# ME126)



#### 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

AN ISO 9001:2015 REGISTERED COMPANY

# spectrum

# ME126, DL-Methionine, FCC

# **Source Statement**

The above-mentioned catalog item is manufactured by chemical synthesis. No animal or plant 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

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Soy
- 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 likely to be 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 72 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

# spectrum®

F.W. 149.21

 $C_5H_{11}NO_2S$ 

# 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.

		5 11 <u>E</u>
<b>USE CARE:</b> 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. <b>KEEP FROM CHILDREN</b>	ME126 SIZ SY DL-Methionine	Assay (C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S; Dried Basis)
	FCC	Lead5 mg/kg Loss on Drying0.5% Residue on Ignition0.1%
	CAS 59-51-8	LIGHT SENSITIVE: Keep tightly closed in light- resistant containers.
	repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.	<b>WARNING:</b> Cancer and Reproductive Harm- www.P65Warnings.ca.gov
	Chemical Emergency: (800)424-9300	
	www.SpectrumChemical.com	G 11/H11GHS ? Lot No. XQ####

#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

Date: 00-00-0000

XD.

769 Jersey Ave. New Brunswick, NJ 08901

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

732.214.1300