

# **Scientific Documentation**

# **Monosodium L-Glutamate, 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 Kosher Certification



# Specification for Monosodium L-Glutamate, FCC (G1038)

Item Number	G1038
Item	Monosodium L-Glutamate, FCC
CAS Number	6106-04-3
Molecular Formula	$C_5H_8NNaO_4$ • $H_2O$
Molecular Weight	187.13
MDL Number	
Synonyms	MSG ; Monosodium L-Glutamate ; L-Glutamic Acid Monosodium Salt

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (C5H8NNaO4; DRIED BASIS)	98.5	101.5 %
OPTICAL ROTATION, [a] 20D (DRIED BASIS)	+24.5° to +25.5°	
CLARITY AND COLOR OF SOLUTION	TO PASS TEST	
CHLORIDE (Cl)		0.2%
LEAD (Pb)		5 mg/kg
LOSS ON DRYING		0.5%
IDENTIFICATION	TO PASS TEST	
CERTIFIED KOSHER		
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

#### 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	G1038	Lot Number	1MK0203
Item	Monosodium L-Glutamate, FCC	CAS Number	6106-04-3
Molecular Formula	$C_5H_8NNaO_4 \cdot H_2O$	Molecular Weight	187.13

тгст	SPECIFICATION		
TEST	MIN	MAX	RESULT
APPEARANCE			WHITE POWDER
ASSAY (C <sub>5</sub> H <sub>8</sub> NNaO <sub>4</sub> ; DRIED BASIS)	98.5	101.5 %	99.1 %
OPTICAL ROTATION, [a] 20D (DRIED BASIS)	+24.5° to +25.5°		+24.9°
CLARITY AND COLOR OF SOLUTION	TO PASS TEST		PASSES TEST
CHLORIDE (CI)		0.2%	<0.1 %
LEAD (Pb)		5 mg/kg	<0.05 mg/kg
LOSS ON DRYING		0.5%	0.2 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			21-DEC-2024
DATE OF MANUFACTURE			22-DEC-2021
MONOGRAPH EDITION			(FCC) 13

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 04-JAN-24 11:47:02

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 10-JAN-24 12:40:46

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 14-June-2022

#### 1. Identification Product identifier **Product Name** MONOSODIUM L-GLUTAMATE, FCC Other means of identification G1038 Product Code(s) **Synonyms** None Recommended use of the chemical and restrictions on use No information available **Recommended use 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 Crystals or Crystalline powder

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-%	Trade secret
L-Glutamic Acid Monosodium Salt	6106-04-3	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

## 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 effered Symptoms	cts, both acute and delayed No information available.	
Indication of any immediate medical attention and special treatment needed		

Note to physicians Treat symptomatically.

#### 5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the 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). Sodium oxides.
Explosion data Sensitivity to mechanical impac	ct 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, include	ing any incompatibilities
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place.

#### 8. Exposure controls/personal protection

#### Control parameters

Exposure LimitsThe following ingredients are the only ingredients of the product above the cut-off level (or<br/>level that contributes to the hazard classification of the mixture) which have an exposure<br/>limit applicable in the region for which this safety data sheet is intended or other<br/>recommended limit. At this time, the other relevant constituents have no known exposure<br/>limits from the sources listed here.

#### Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
Individual protection measures, suc	ch 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 Color Odor Odor threshold	Crystals or Crystalline powder White No information available No information available	
Property pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air	Values Neutral 230 °C / 446 °F no data available no data available no data available no data available	Remarks • Method None known None known None known None known None known None known None known
Upper flammability or explosive limits Lower flammability or explosive limits Vapor pressure Vapor density	No data available No data available No data available no data available	None known None known
Relative density Water solubility Solubility(ies) Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity	1.6 Soluble in water Sparingly soluble in alcohol No data available no data available >247 - °C °F no data available	None known None known None known None known None known None known None known
Dynamic viscosity <u>Other information</u> Explosive properties Oxidizing properties Softening point Molecular weight VOC Content (%) Liquid Density Bulk density	No data available No information available	None known

# 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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
L-Glutamic Acid Monosodium	= 15800 mg/kg (Rat)	-	-
Salt			
6106-04-3			

#### 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
RID	not regulated
ADR	not regulated
ADN	not regulated

#### 15. Regulatory information

International Inventories

TSCA	Not listed
Note	*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements
DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS AICS	Complies Does not Comply This product complies with ENCS: This product complies with China: Does not Comply Complies 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 hazards0Flammability0Instability0Physical and chemical properties-HMIS-Health hazards0Flammability0Physical hazards0Personal protectionX

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

Legend Sect	ion 8: EXPOSURE CONTROLS/PERSON	AL PROTECTION
TWA	TWA (time-weighted average)	STEL
Ceiling	Maximum limit value	

STEL (Short Term Exposure Limit)

#### 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, Fundicide, 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 date14-June-2022Revision NoteNo information available.DisclaimerNo

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



December 15, 2021

#### 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
G1038	Monosodium L-Glutamate, 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>gualityassurance@spectrumchemical.com</u>

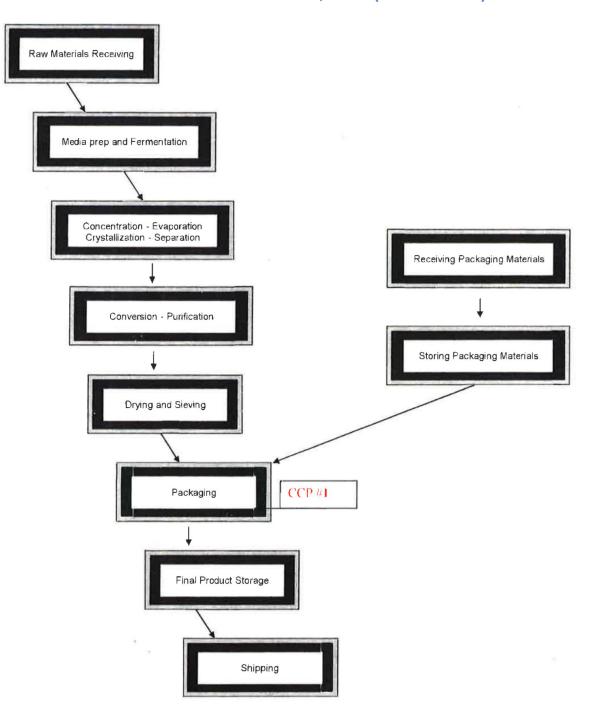
Sincerely,

Outer Clamy

Oralia Chavez Quality Assurance Specialist



# Manufacturing Process Flowchart Monosodium L-Glutamate, FCC (Cat# G1038)



#### 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

# spectrum

# G1038, Monosodium L-Glutamate, FCC

## **Source Statement**

The above mentioned catalog item is manufactured by fermentation of corn syrup. 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
- Latex
- Sulfites > 10 ppm

# **GMO Statement**

The above mentioned catalog cannot be certified as free of genetically modified organisms. However, the manufacturing steps employed subsequent to fermentation during material production (separation, extensive purification and crystallization) would eliminate or dramatically reduce any conceivable contaminant of 'GMO-like' material that might have been present in the fermentation broth.

# **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 been tested on animals for regulatory compliance purposes.

# **Organic Compliance Statement**

The above mentioned catalog item has not been produced using irradiation or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 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:

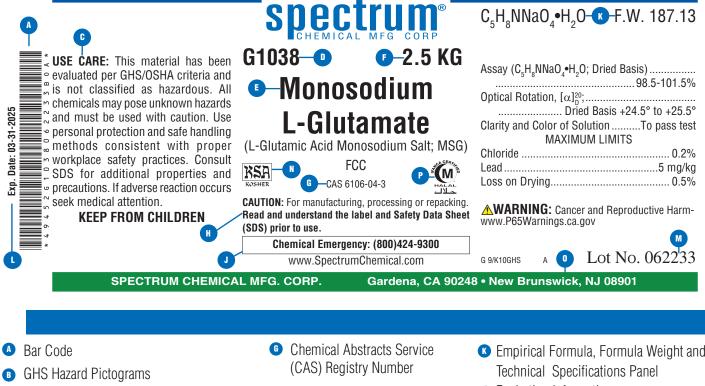
- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

# **spectrum**<sup>®</sup>

# 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.



- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Size/Quantity

- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical **Emergency Telephone Number**
- C Empirical Formula, Formula Weight and
- Expiration Information
- Lot Number
- 🔊 Kosher Certified by Kosher Supervision of America (KSA).
- Storage Color Band
- Halal Certified by IFANCA
- bioCertified

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

## Spectrum Chemical Mfg Corp

recommendations when storing hazardous chemicals.

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

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

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

732.214.1300



בס"ד Jan 18, 2024

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 Brand UKD-ID D/P/M	G1038, Monosodium L-Glutamate, FCC Spectrum KSAV3-E5M7E53 P
	Symbol Required	KSA
This certificate expires on <b>Feb 01, 2025</b>	<b>Special Conditions</b>	

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.

ocument id: -1108132 P.O.Box 35721, Los Angeles, Ca 90035 - (310) 282-0444 - Fax (310) 282-0505 - Email info@ksakosher.com - www.ksakosher.com