

Scientific Documentation

Methenamine, 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 Methenamine, USP (M1447)

Item Number	M1447
Item	Methenamine, USP
CAS Number	100-97-0
Molecular Formula	$C_6H_{12}N_4$
Molecular Weight	140.19
MDL Number	
Synonyms	Methenamine ; Hexamine ; Hexamethylenetetramine

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	FORMALDEHYDE IS LIBERATED AND AMMONIA IS EVOLVE	
ASSAY (DRIED BASIS)	99.0	100.5%
LOSS ON DRYING		2.0%
RESIDUE ON IGNITION		0.1%
CHLORIDE (Cl)		0.014 %
SULFATE	NO TURBIDITY IS PRODUCE WITHIN 1 MINUTE	
AMMONIUM SALTS	THE MIXTURE IS NOT DARKER IN COLOR THAN A MIXTURE OF 1 mL OF THE REAGENT AND 10 mL OF WATER	
ELEMENTAL IMPURITIES		AS REPORTED
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 2 (SOLVENT) / METHANOL	.	
MONOGRAPH EDITION		
EXPIRATION DATE		
DATE OF MANUFACTURE		

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	M1447	Lot Number	1LH1257
Item	Methenamine, USP	Manufacturer Lot	H20220202
CAS Number	100-97-0	Manufacturer Code	3771
Molecular Formula	C ₆ H ₁₂ N ₄	Molecular Weight	140.19

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE CRYSTALS
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	FORMALDEHYDE IS LIBERATED AND AMMONIA IS EVOLVE		FORMALDEHYDE IS LIBERATED AND AMMONIA IS EVOLVE
ASSAY (DRIED BASIS)	99.0	100.5%	99.6 (M)
LOSS ON DRYING		2.0%	0.6 (M)
RESIDUE ON IGNITION		0.1%	0.05 (M)
CHLORIDE (CI)		0.014 %	<0.014 (M)
SULFATE	NO TURBIDITY IS PRODUCE WITHIN 1 MINUTE		NO TURBIDITY IS PRODUCE WITHIN 1 MINUTE (M)
AMMONIUM SALTS	THE MIXTURE IS NOT DARKER IN COLOR THAN A MIXTURE OF 1 mL OF THE REAGENT AND 10 mL OF WATER		COMPLIES (M)
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT NO ELEMENTAL IMPURITIES PRESENT (M)

TEST	SPECIFICATION		RESULT
	MIN	MAX	
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL	.		<3000 ppm (M)
MONOGRAPH EDITION			(USP) 2022
EXPIRATION DATE			28-FEB-2025
DATE OF MANUFACTURE			01-FEB-2022
NOTE:All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
14-SEP-22 13:28:21

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



Certificate of Analysis Results Approved By:

JAMAYA
Javier Amaya
14-SEP-22 13:29:53

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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by GUANGZHOU HANPU PHARMACEUTICAL CO LTD at No.9, Jufeng North Road, Aotou Town, Conghua City, GUANGZHOU, Guangdong 510940, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

spectrum®



Revision date 06-January-2022

Revision Number 2

1. Identification

Product identifier

Product Name METHENAMINE, USP

Other means of identification

Product Code(s) M1447

UN/ID no UN1328

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

Serious eye damage/eye irritation	Category 2B
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Flammable solids	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Causes eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction

Flammable solid



Appearance Crystalline powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Avoid breathing dust/fume/gas/mist/vapors/spray

In case of inadequate ventilation wear respiratory protection

Contaminated work clothing must not be allowed out of the workplace

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Ground/bond container and receiving equipment

Use explosion-proof electrical/ ventilating / lighting/ .? / equipment

Wear protective gloves/eye protection/face protection

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

IF ON SKIN: Wash with plenty of water and soap

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing

If experiencing respiratory symptoms: Call a POISON CENTER or doctor

In case of fire: Use CO₂, dry chemical, or foam to extinguish

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

Causes mild skin irritation.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Methenamine	100-97-0	100	*

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

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Get immediate medical advice/attention.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open

while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin contact

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

Ingestion

May produce an allergic reaction. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

Self-protection of the first aider

Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

Symptoms

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. Prolonged contact may cause redness and irritation.

Indication of any immediate medical attention and special treatment needed

Note to physicians

May cause sensitization in susceptible persons. Treat symptomatically.

5. Fire-fighting measures

**Suitable Extinguishing Media
Large Fire**

Dry chemical. Carbon dioxide (CO₂). water spray. Alcohol resistant foam.
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

risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Product is or contains a sensitizer. May cause sensitization by inhalation and skin contact. May cause sensitization by skin contact.

Hazardous combustion products

Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO_x).

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

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

Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.

Other information

Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Keep out of drains, sewers, ditches and waterways.
Methods for cleaning up	Take precautionary measures against static discharges. Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Very hygroscopic; protect from moisture. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep at a temperature not exceeding 25 °C. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. Keep out of the reach of children.
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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.
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Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Tight sealing safety goggles.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.

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	Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder
Color	Colorless; White
Odor	Odorless
Odor threshold	No information available

Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	263 - 280 °C / 505.4 - 536 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	250 °C / 482 °F	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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	4.9	None known
Relative density	1.33	None known
Water solubility	Soluble in cold water	None known
Solubility(ies)	Soluble in Ethanol Insoluble in diethyl ether Insoluble in Chloroform Insoluble in Alcohol	None known
Partition coefficient	-2.84	None known
Autoignition temperature	> 371 °C / 699.8 °F	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	140.19
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Heat, flames and sparks.

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

Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause sensitization in susceptible persons. (based on components).
Eye contact	Specific test data for the substance or mixture is not available. Causes eye irritation. May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May cause sensitization by skin contact. Causes mild skin irritation.
Ingestion	Specific test data for the substance or mixture is not available. May cause additional affects as listed under "Inhalation".

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Itching. Rashes. Hives. May cause redness and tearing of the eyes. Prolonged contact may cause redness and irritation.
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Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methenamine 100-97-0	> 20000 mg/kg (Rat)	> 2000 mg/kg (Rat)	-

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

Skin corrosion/irritation	May cause skin irritation. Classification based on data available for ingredients.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Irritating to eyes.
Respiratory or skin sensitization	May cause sensitization by inhalation. May cause sensitization by skin contact.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	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	Crustacea
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			microorganisms	
Methenamine 100-97-0	-	LC50: 44600 - 55600mg/L (96h, Pimephales promelas)	-	EC50: 29868 - 43390mg/L (48h, Daphnia magna)

Persistence and degradability No information available.
Bioaccumulation Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

14. Transport information

DOT

UN/ID no UN1328
Proper Shipping Name: Hexamethylenetetramine
Hazard class 4.1
Packing group: III
Special Provisions A1, IB8, IP3, T1, TP33
Marine Pollutant Severe Marine Pollutant
Description: UN1328, Hexamethylenetetramine, 4.1, III
Emergency Response Guide Number 133

TDG

UN-No: UN1328
Proper Shipping Name: Hexamethylenetetramine
Hazard class 4.1
Packing Group: III
Description: UN1328, Hexamethylenetetramine, 4.1, III

MEX

UN-No UN1328
Proper Shipping Name Hexamethylenetetramine
Hazard class 4.1
Packing Group III
Description UN1328, Hexamethylenetetramine, 4.1, III

ICAO (air)

UN-No: UN1328
Proper Shipping Name: Hexamethylenetetramine
Hazard class 4.1
Packing Group: III
Description: UN1328, Hexamethylenetetramine, 4.1, III

IATA

UN number UN1328
Proper Shipping Name: Hexamethylenetetramine
Transport hazard class(es) 4.1
Packing group III
Description: UN1328, Hexamethylenetetramine, 4.1, III

IMDG

UN number	UN1328
Proper shipping name	Hexamethylenetetramine
Transport hazard class(es)	4.1
Packing group	III
EmS-No	F-A, S-G
Marine pollutant	NP1
Description	UN1328, Hexamethylenetetramine, 4.1, III

RID

UN number	UN1328
Proper Shipping Name:	Hexamethylenetetramine
Transport hazard class(es)	4.1
Packing group	III
Classification code	F1
Description:	UN1328, Hexamethylenetetramine, 4.1, III
Labels	4.1

ADR

UN number	1328
Proper Shipping Name:	Hexamethylene-tetramine
Transport hazard class(es)	4.1
Packing group	III
Classification code	F1
Tunnel restriction code	(E)
Description:	1328, Hexamethylene-tetramine, 4.1, III, (E)
Labels	4.1

ADN

UN/ID No	UN1328
Proper shipping name	Hexamethylenetetramine
Transport hazard class(es)	4.1
Packing Group	III
Classification code	F1
Description	UN1328, Hexamethylenetetramine, 4.1, III
Hazard label(s)	4.1
Limited quantity (LQ)	5 kg
Equipment Requirements	PP

15. Regulatory information

International Inventories

TSCA	Complies
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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 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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Methenamine 100-97-0	0996	-	-

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 1

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2 *

Flammability 1

Physical hazards 0

Personal protection X

Chronic Hazard Star Legend

** = Chronic Health Hazard*

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 06-January-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



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
M1447	Methenamine, 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,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

M1447, Methenamine, USP

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
- 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 36 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Methenamine, USP (Cat# M1447)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 - Methenamine, USP (Cat# M1447)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Ethanol	3	< 5000 ppm

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

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

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.

DANGER

- Flammable solid • May cause an allergic skin reaction • May cause allergy or asthma symptoms or breathing difficulties if inhaled • Causes eye irritation
- Causes mild skin irritation.
- Keep away from heat, sparks, open flames, hot surfaces • No smoking • Ground container and receiving equipment • Use explosion-proof equipment • Do not eat, drink or smoke when using this product • Wear respiratory protection, eye protection, face protection, protective gloves • Do not breathe dust • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or physician. IN CASE OF FIRE: Use an approved dry powder, alcohol-resistant foam, CO₂ or water spray to extinguish.

KEEP FROM CHILDREN

M1447

SIZ SY

Methenamine
(Hexamethylenetetramine;
Hexamine)
USP
CAS 100-97-0

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

DOT: UN1328, Hexamethylenetetramine, 4.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_6H_{12}N_4$ F.W. 140.19

Manufacturer/Supplier Code ?
Manufacturer Lot Number..... ?

Assay (Dried Basis).....99.0-100.5%

MAXIMUM LIMITS

Loss on Drying.....2.0%
Residue on Ignition.....0.1%
Chloride0.014%
Sulfate.....To pass test
Ammonium SaltsTo pass test
Elemental ImpuritiesAs reported
Residual SolventsTo pass test

HYGROSCOPIC: Keep tightly closed. Store below 25°C.

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

Repackaged by Spectrum as:
Lot No. XQ####

Exp. Date: 00-00-0000



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