

Scientific Documentation

Azathioprine, 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 Azathioprine, USP (A1383)

Item Number	A1383
Item	Azathioprine, USP
CAS Number	446-86-6
Molecular Formula	C ₉ H ₇ N ₇ O ₂ S
Molecular Weight	277.26
MDL Number	
Synonyms	6-(1-Methyl-4-nitroimidazol-5-ylthio)purine

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
LOSS ON DRYING		1.0 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES:		
AZATHIOPRINE RELATED COMPOUND A		0.15 %
MERCAPTOPURINE		0.15 %
AZATHIOPRINE RELATED COMPOUND G		0.10 %
ANY OTHER UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
ELEMENTAL IMPURITIES	AS REPORTED	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:
769 Jersey Ave. 14422 S. San Pedro St.

Spectrum Chemical Mfg Corp

Corporate Headquarters: ***West Coast Facility:***

New Brunswick, NJ 08901 Gardena, CA 90248

732.214.1300

310.516.8000

Certificate Of Analysis

Item Number	A1383	Lot Number	4MG0022
Item	Azathioprine, USP	Manufacturer Lot	AZ-21206
CAS Number	446-86-6	Manufacturer Code	14093
Molecular Formula	C ₉ H ₇ N ₇ O ₂ S	Molecular Weight	277.26

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	102.0 %	101.7 %
LOSS ON DRYING		1.0 %	1.0 %
RESIDUE ON IGNITION		0.1 %	0.1%
ORGANIC IMPURITIES:			.
AZATHIOPRINE RELATED COMPOUND A		0.15 %	<0.15 % (M)
MERCAPTOPURINE		0.15 %	<0.15 % (M)
AZATHIOPRINE RELATED COMPOUND G		0.10 %	NOT DETECTED (M)
ANY OTHER UNSPECIFIED IMPURITY		0.10 %	0.06 % (M)
TOTAL IMPURITIES		0.5 %	0.06 % (M)
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD (M)
APPEARANCE			PALE YELLOW POWDER
EXPIRATION DATE			31-MAY-2026
DATE OF MANUFACTURE			01-JUN-2021
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / PYRIDINE			<200 ppm (M)
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
CLASS 3 (solvent) / ACETONE			<5000 ppm (M)

TEST	SPECIFICATION		RESULT
	MIN	MAX	
NOTE:All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

TDAO
Tiffany DAO
27-JUL-23 05:30:18

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA
Genaro Herrera
27-JUL-23 06:15:49

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 AARTI PHARMALABS LIMITED at Unit - IV, Plot No: E - 50, 50/1, 59/1, M.I.D.C. Tarapur, Taluka & District: Palghar, Tarapur, Maharashtra 401506, India (IND). 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

Preparation Date: 04/27/2015

Revision date 03/12/2019

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: A1383
Product Name: AZATHIOPRINE, USP

Other means of identification

Synonyms: 1H-Purine,6-((1-methyl-4-nitro-1H-imidazol-5-yl)thio)-
 ((1-Methyl-4-nitro-1H-imidazol-5-yl)thio)-1H-purine
 (Methyl-p-nitro-5-imidazolyl)-thiopurine
 (1'-Methyl-4'-nitro-5'-imidazolyl)-mercaptapurine

CAS #: 446-86-6
RTECS # UO8925000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 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: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2A
Skin sensitization	Category 1B
Carcinogenicity	Category 1A
Reproductive toxicity	Category 2

Label elements

Danger

Hazard statements
 Harmful if swallowed
 Causes serious eye irritation

May cause an allergic skin reaction
May cause cancer
Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Use personal protective equipment as required
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing must not be allowed out of the workplace
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

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

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

Wash contaminated clothing before reuse

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Azathioprine	446-86-6	100

4. FIRST AID MEASURES

First aid measures

General Advice:

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention.

Product code: A1383

Product name: AZATHIOPRINE, USP

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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. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms Causes serious eye irritation
Causes eye irritation
May cause an allergic skin reaction
Coughing
Ingestion may cause nausea, vomiting, and diarrhea
Fever
tiredness
Weakness
Joint pain
May cause lower back pain or side pain

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 Carbon monoxide. Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Sulfur oxides.

Specific hazards May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters: 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

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. 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. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Sensitive to light. Store in light-resistant containers. 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:

Alkalis

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Azathioprine	446-86-6	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Azathioprine	446-86-6	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Azathioprine	446-86-6	None	None

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:	Goggles or Safety glasses with side-shields.
Skin and body protection:	Chemical resistant apron Gloves Long sleeved clothing
Respiratory protection:	Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
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

Physical state: Solid	Appearance: Powder.	Color: Light yellow.
Odor: Odorless.	Taste No information available.	Formula C9H7N7O2S
Molecular/Formula weight (g/mole): 277.26	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): No information available	Decomposition temperature(°C/°F): 243°C/469.4°F
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water):	

No information available

Viscosity:

No information available

Miscibility:

No information available

Solubility:

Insoluble in cold water

10. STABILITY AND REACTIVITY

Reactivity

Reactive with alkalis

Reactive with oxidizing agents

Chemical stability

Stability:

Sensitive to light. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid:

Heat. Ignition sources. Incompatible materials. Exposure to light.

Incompatible Materials:

Alkalis

Strong oxidizing agents

Hazardous decomposition products:

Carbon oxides. Nitrogen oxides (NO_x). Sulfur oxides.

Other Information

Corrosivity:

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

Azathioprine

CAS No 446-86-6

LD50/oral/rat = 400 mg/kg Oral LD50 Rat

LD50/oral/mouse = 1389 mg/kg Oral LD50 Mouse

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

Value - Acute Tox = 400 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 1389 mg/kg

LD50/dermal/rabbit
Value - Acute Tox = 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 allergic skin reaction.

Eye Contact: Causes serious eye irritation.

Inhalation Causes upper respiratory tract and mucous membrane irritation. Symptoms may include cough and hoarseness.

Ingestion Harmful if swallowed. Can cause gastrointestinal tract disturbances, slightly bitter taste in mouth, nausea, vomiting, hypermotility, and diarrhea. May affect urinary system/kidneys (renal failure, acute tubular necrosis), blood (leukopenia, thrombocytopenia, macrocytic anemia, changes in white blood cell count), cardiovascular system, liver (elevation in liver enzymes), musculoskeletal system. Other symptoms may include fever, chills, painful or difficult urination, unusual tiredness or weakness, joint pain, lower back or side pain, skin rash or red spots on skin, unusual bleeding or bruising, blood in urine or stools, infection, death.

Aspiration hazard No information available.

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

Chronic Toxicity Skin: Prolonged or repeated exposure may cause allergic reactions (dermatitis or asthma) in certain sensitive individuals if inhaled, ingested or in contact with skin. Ingestion: May affect liver, blood (macrocytic anemia, thrombocytopenia, leukopenia, changes in white blood cell count) and cause bone marrow hypoplasia/depression, immunosuppression (decrease in immune response), cancer, weight loss/anorexia.

Sensitization: May cause sensitization by skin contact.

Mutagenic Effects: Experiments with bacteria and/or yeast have shown mutagenic effects
May affect genetic material

Carcinogenic effects: May cause cancer.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic	Australia - Prohibited Carcinogenic
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						Substances	Substances
Azathioprine	446-86-6	Group 1 - Carcinogenic - Monograph 100A [2012] Supplement 7 [1987] Monograph 26 [1981]	Not listed	Known Human Carcinogen	Present	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity

Suspected of damaging fertility or the unborn child

Reproductive Effects:

May cause adverse reproductive effects

Developmental Effects:

No information available

Teratogenic Effects:

May cause birth defects (teratogenic effects)

Specific Target Organ Toxicity

STOT - single exposure

No information available.

STOT - repeated exposure

No information available.

Target Organs:

Bladder. Blood. Bone Marrow. Cardiovascular system. Immune system. Liver.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:

No data available.

Persistence and degradability:

No information available

Bioaccumulative potential:

No information available.

Mobility in soil

No information available

Other adverse effects

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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Azathioprine	446-86-6	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class	No information available
Subsidiary Class	No information available
Packing group:	No information available
Emergency Response Guide Number	No information available
Marine Pollutant	No data available
DOT RQ (lbs):	No information available
Special Provisions	No Information available
Symbol(s):	No information available
Description:	No information available

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
Marine Pollutant	No Information available
Description:	No information available

ADR

UN Number	Not regulated
Proper Shipping Name:	No information available
Transport hazard class(es)	No information available
Packing group	No information available
Subsidiary Risk:	No information available

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
Marine Pollutant	No information available

RID

UN Number	Not Regulated
Proper Shipping Name:	No information available
Transport hazard class(es)	No information available
Subsidiary Risk:	No information available
Packing group	No information available

ICAO (air)

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

IATA

UN Number	Not Regulated
Proper Shipping Name:	No information available
Transport hazard class(es)	No information available
Subsidiary Risk:	No information available
Packing group	No information available

Precautionary Statements - No information available
Response
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Azathioprine	446-86-6	Not Listed	Present KE-24461	Not present	Present (9)-1448	Not listed	Present	Present 207-175-4


U.S. Regulations

Azathioprine


Massachusetts RTK: Present
Pennsylvania RTK: Special hazardous substance
Pennsylvania RTK - Special Hazardous Substances Present
Minnesota - Hazardous Substance List: Present
New York Release Reporting - List of Hazardous Substances:
 1 lb RQ
California Directors List of Hazardous Substances: Present

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

 **WARNING:** This product contains a chemical known to the State of California to cause cancer. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

 **WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Azathioprine	446-86-6	carcinogen	developmental toxicity	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Azathioprine	446-86-6	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Azathioprine	446-86-6	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Azathioprine	446-86-6	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Azathioprine	446-86-6	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Azathioprine	446-86-6	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Azathioprine	446-86-6	

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed

R45 - May cause cancer

R43 - May cause sensitization by skin contact

S -phrase(s)

S 2 - Keep out of the reach of children.

S46 - If swallowed, seek medical advice immediately and show this container or label

S53 - Avoid exposure - obtain special instructions before use

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Azathioprine	446-86-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful

Xn



16. OTHER INFORMATION

Preparation Date: 04/27/2015

Revision date: 03/12/2019

Product code: A1383

Product name: AZATHIOPRINE, USP

Page

Prepared by:

Sonia Owen

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 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
A1383	Azathioprine, 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

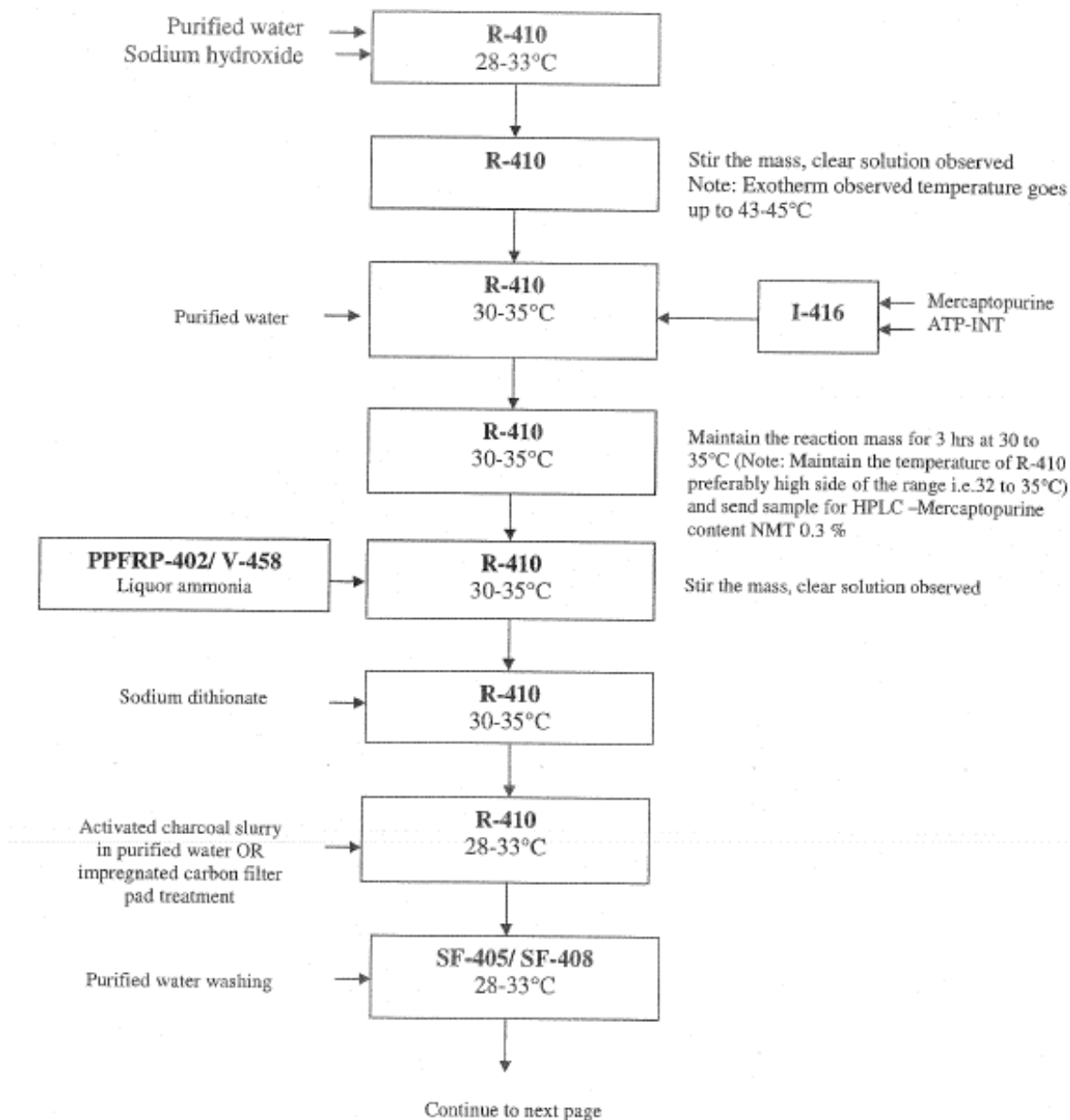
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Azathioprine, USP (Cat# A1383)

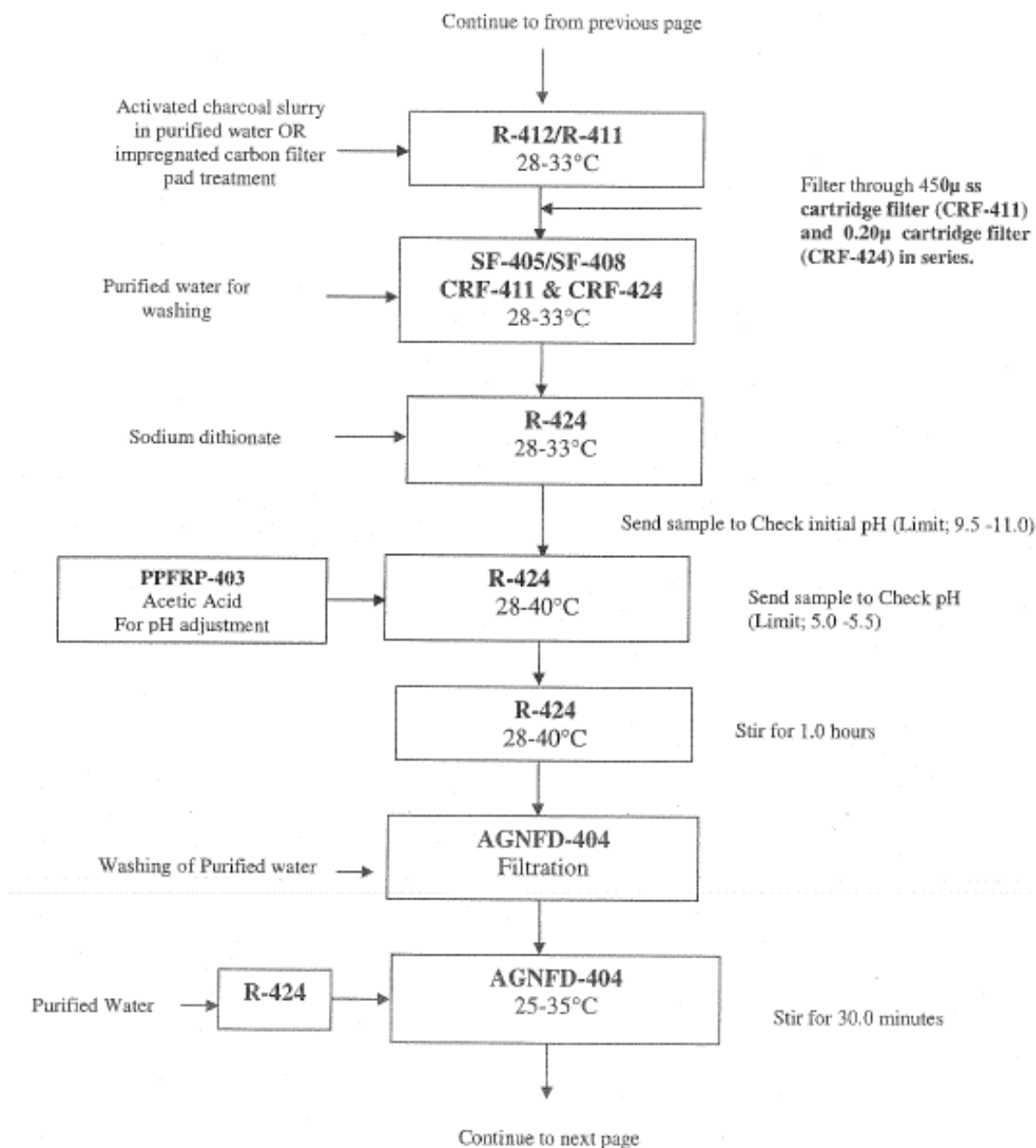


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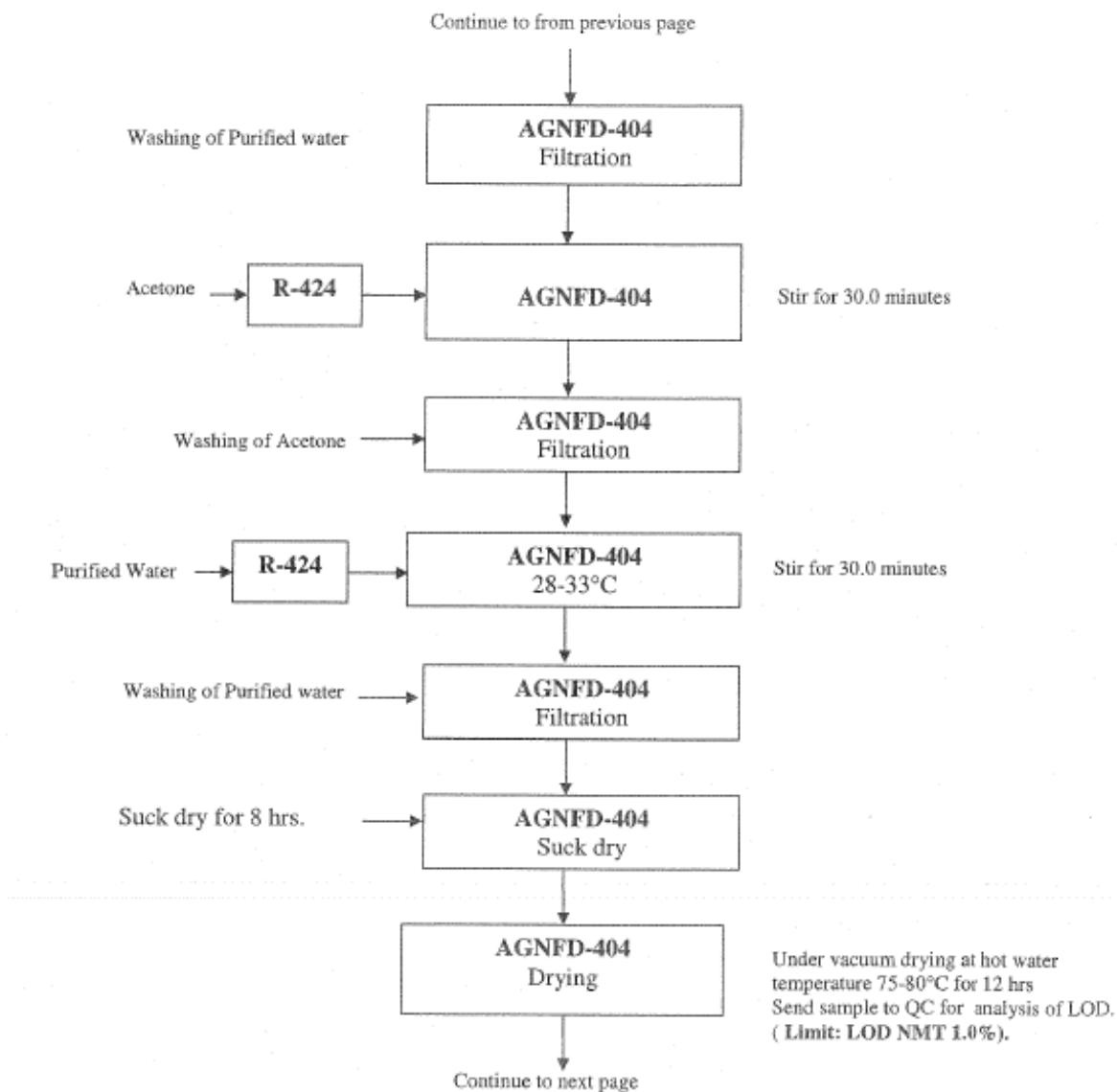
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WEST COAST FACILITY

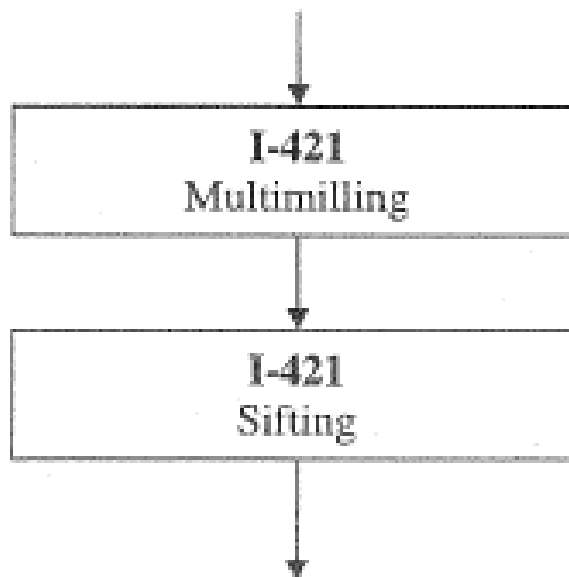
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Continue to from previous page



Azathioprine

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

A1383, Azathioprine, 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 above mentioned catalog item 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 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Azathioprine, USP (Cat# A1383)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.00009 ppm
Lead	Pb	1	< 0.00188 ppm
Arsenic	As	1	< 0.00115 ppm
Mercury	Hg	1	< 0.02129 ppm
Cobalt	Co	2A	< 0.00063 ppm
Vanadium	V	2A	< 0.00211 ppm
Nickel	Ni	2A	< 0.02732 ppm

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

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

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RE: Residual Solvents - Azathioprine, USP (Cat# A1383)

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
Pyridine	2	< 200 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm

No Class1 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
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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.

A **DANGER**

C • Harmful if swallowed • Causes serious eye irritation • May cause an allergic skin reaction • May cause cancer • Suspected of damaging fertility or the unborn child.

B • Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Avoid breathing dust • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.

L **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 exposed or concerned: Get medical attention.

J **KEEP FROM CHILDREN**

spectrum®
CHEMICAL MFG CORP

A1383 **D** **F-1 KG**

Azathioprine

E **USP**

G **CAS 446-86-6**

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

USP 800
HAZARDOUS DRUG

K **C₉H₇N₇O₂S** **F.W. 277.26**

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%

MAXIMUM LIMITS

Loss on Drying 1.0%
Residue on Ignition 0.1%

Organic Impurities:

Azathioprine Related Compound A 0.15%
Mercaptopurine 0.15%
Azathioprine Related Compound G 0.10%
Any Other Unspecified Impurity 0.10%
Total Impurities 0.5%
Elemental Impurities As reported
Residual Solvents To pass test

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

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

M Repackaged by Spectrum as:

N **Lot No. 062233**

O **Storage Color Band**

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|---|--|---|
| A Bar Code | F Size/Quantity | K Empirical Formula, Formula Weight and Technical Specifications Panel |
| B GHS Hazard Pictograms | G Chemical Abstracts Service (CAS) Registry Number | L Expiration Information |
| C Warning, Safety Data and Precautionary Information | H Caution Information | M Lot Number |
| D Product Catalog Number | I DOT Shipping Information | N Kosher Certified by Kosher Supervision of America (KSA). |
| E Item Name, Form, Grade | J Toll-Free 24-Hour Chemical Emergency Telephone Number | |
| O Storage Color Band | | |

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 recommendations when storing hazardous chemicals.

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

Spectrum Chemical Mfg Corp

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