

Scientific Documentation

Pantoprazole Sodium, 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 Pantoprazole Sodium, USP (P3714)

Item Number	P3714
Item	Pantoprazole Sodium, USP
CAS Number	164579-32-2
Molecular Formula	C ₁₆ H ₁₄ F ₂ N ₃ NaO ₄ S•1.5H ₂ O
Molecular Weight	432.37
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
WATER DETERMINATION	5.0	8.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES TEST 2:		
PANTOPRAZOLE RELATED COMPOUND C		0.10 %
PANTOPRAZOLE RELATED COMPOUND A		0.20 %
PANTOPRAZOLE RELATED COMPOUND D & E		0.20 %
PANTOPRAZOLE RELATED COMPOUND E		0.10 %
PANTOPRAZOLE RELATED COMPOUND B		0.15 %
ANY OTHER INDIVIDUAL IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (C)	POSITIVE FOR SODIUM	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

<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	P3714	Lot Number	4MJ0045
Item	Pantoprazole Sodium, USP	Manufacturer Lot	PAT/0322007
CAS Number	164579-32-2	Manufacturer Code	14107
Molecular Formula	C16H14F2N3NaO4S•1.5H2O	Molecular Weight	432.37

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	100.1 % (M)
WATER DETERMINATION	5.0	8.0 %	6.6 % (M)
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
ORGANIC IMPURITIES TEST 2:			.
PANTOPRAZOLE RELATED COMPOUND C		0.10 %	< 0.05 % (M)
PANTOPRAZOLE RELATED COMPOUND A		0.20 %	NONE DETECTED (M)
PANTOPRAZOLE RELATED COMPOUND D & E		0.20 %	< 0.05 % (M)
PANTOPRAZOLE RELATED COMPOUND E		0.10 %	0.05 % (M)
PANTOPRAZOLE RELATED COMPOUND B		0.15 %	0.05 % (M)
ANY OTHER INDIVIDUAL IMPURITY		0.10 %	< 0.05 % (M)
TOTAL IMPURITIES		0.5 %	0.05 % (M)
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD (M)
IDENTIFICATION (C)	POSITIVE FOR SODIUM		POSITIVE FOR SODIUM
EXPIRATION DATE			31-AUG-2025

TEST	SPECIFICATION		RESULT
	MIN	MAX	
DATE OF MANUFACTURE			01-SEP-2020
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 2 (solvent) / ACETONITRILE			<410 PPM (M)
CLASS 2 (solvent) / CHLOROFORM			<60 PPM (M)
CLASS 2 (SOLVENT) / METHANOL			<3000 PPM (M)
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 PPM (M)
CLASS 2 (solvent) / TOLUENE			<890 PPM (M)
CLASS 3 (solvent) / ACETONE			<5000 PPM (M)
NOTE:All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

MCAMACHO
Matheu Camacho
31-OCT-23 09:57:27

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
31-OCT-23 09:57:46

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.

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 SMS Pharmaceuticals Limited at Unit-VII, Kandivalasa (V), Poosapatirega (M), Vizianagaram District, Andhra Pradesh 535204, 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: 9/19/2017

Revision date 08/09/2019

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: P3714
Product Name: Pantoprazole Sodium, USP

Other means of identification

Synonyms: 1H-Benzimidazole,
 6-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-, sodium salt,
 hydrate (2:2:3) (CA INDEX NAME)
 1H-Benzimidazole,
 5-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-, sodium salt,
 hydrate (2:3) (9CI)
 Pantoprazole sodium hydrate
 Pantoprazole sodium sesquihydrate

CAS #: 164579-32-2; 138786-67-1 (for anhydrous form)
RTECS # DD8264000 (for anhydrous form)
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
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Label elements

Warning

Hazard statements

Product code: P3714

Product name: Pantoprazole Sodium,
 USP

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Harmful if swallowed



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell
Rinse mouth

Precautionary Statements - Disposal

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Pantoprazole Sodium	164579-32-2	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.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention if irritation occurs.

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

May cause eye/skin/respiratory tract irritation
May cause abdominal pain, nausea, vomiting, diarrhea
May cause constipation
May cause dyspepsia
Flatulence

May cause loss of appetite
Blurred vision
Coughing
May affect the liver
Headache
Joint pain
May cause drowsiness or dizziness
tiredness
Weakness
Dyspnea (Difficulty breathing and shortness of breath)

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:

Dry chemical. Carbon dioxide (CO₂). Water spray mist or foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical

Hazardous combustion products

Carbon dioxide (CO₂). Hydrocarbons. Sulfur oxides. Produce toxic and/or corrosive substances on contact with water. Flammable/toxic gases may accumulate in tanks and hopper cars.

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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective 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 from entering into soil, ditches, sewers, waterways, and/or ground water.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents
Strong bases
Strong acids

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Pantoprazole Sodium	164579-32-2	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British	Canada - Ontario	Canada - Quebec
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			Columbia		
Pantoprazole Sodium	164579-32-2	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Pantoprazole Sodium	164579-32-2	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:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Effective dust mask. 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: Crystalline powder.	Color: White. Off-white.
Odor: No information available.	Taste No information available.	Formula C16-H14-F2-N3-Na-O4-S.1.5H2O
Molecular/Formula weight (g/mole): 432.37	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not applicable	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 139-140 °C/282.2-284 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available

Specific gravity:

Product code: P3714

Product name: Pantoprazole Sodium,
USP

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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:
Freely soluble in Methanol
Very soluble in Ethanol
Insoluble in Hexane
Practically insoluble in Dichloromethane

10. STABILITY AND REACTIVITY

Reactivity
No information available

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials. Ignition sources.

Incompatible Materials: Strong oxidizing agents
Strong bases
Strong acids

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Sulfur oxides. Sodium oxides. Hydrogen fluoride.

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

Pantoprazole Sodium	
CAS No	164579-32-2

LD50/oral/rat = No information available

LD50/oral/mouse = No information available

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 = 747 mg/kg Oral LD50 Rat; >1000 mg/kg Oral LD50 Mouse (for anhydrous form CAS no. 138786-67-1)

Product Information

LD50/oral/rat =
Value - Acute Toxicity = 747 mg/kg

LD50/oral/mouse =
Value - Acute Tox = >1000 mg/kg

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.
Inhalation	May cause irritation of respiratory tract.
Ingestion	Harmful if swallowed. May cause abdominal pain, nausea, vomiting, diarrhea. May cause constipation. May cause dyspepsia. May cause flatulence. May cause loss of appetite. May affect behavior/central nervous system (dizziness, headache). It may affect behavior/central nervous system (drowsiness). May affect behavior/central nervous system (tiredness). May cause weakness. May cause joint pain. May cause chest pain. May cause blurred or foggy vision. May cause coughing. May affect behavior/central nervous system (confusion). May also cause anxiety and stress. May affect the liver (liver function tests are abnormal). May affect respiration (dyspnea - difficulty breathing and shortness of breath).
Aspiration hazard	No information available.

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

Chronic Toxicity	No information available.
Sensitization:	No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Pantoprazole Sodium	164579-32-2	Not listed	Not listed	Not listed	Not listed	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 No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility 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
Pantoprazole Sodium	164579-32-2	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
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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 - Response No information available
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.
<i>Pantoprazole Sodium</i>	164579-32-2	Not Listed	Not present	Not present	Not present	Not listed	Not listed	Not present

U.S. Regulations

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

Chemicals Known to the State of California to Cause Cancer:
 This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:
 This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Pantoprazole Sodium	164579-32-2	Not Listed	Not Listed	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
<i>Pantoprazole Sodium</i>	164579-32-2	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
Pantoprazole Sodium	164579-32-2	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)
Pantoprazole Sodium	164579-32-2	Not Listed	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Pantoprazole Sodium	164579-32-2	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Pantoprazole Sodium	164579-32-2	Not listed

EU Classification**EU GHS - SV - CLP 1272/2008**

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Pantoprazole Sodium	164579-32-2	

EU - CLP (1272/2008)**R-phrases(s)**

R22 - Harmful if swallowed

S -phrase(s)

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

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Pantoprazole Sodium	164579-32-2		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC**Indication of danger:**

Xn - Harmful

Xi**16. OTHER INFORMATION**

Preparation Date: 9/19/2017
Revision date 08/09/2019
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
P3714	Pantoprazole Sodium, 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

P3714, Pantoprazole Sodium, 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 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 - Pantoprazole Sodium, USP (Cat# P3714)

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 - Pantoprazole Sodium, USP (Cat# P3714)

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
Acetonitrile	2	< 410 ppm
Chloroform	2	< 60 ppm
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm

No Class 1 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.

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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. Below you will find a typical label example for this catalog item.

WARNING

- Harmful if swallowed.
- Do not eat, drink or smoke when using this product • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.

KEEP FROM CHILDREN

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



P3714 **SIZ SY**

Pantoprazole Sodium

USP

CAS 164579-32-2

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

$C_{16}H_{14}F_2N_3NaO_4S \cdot 1.5H_2O$
F.W. 432.37

Manufacturer/Supplier Code	?
Manufacturer Lot Number	?
Assay (Anhydrous Basis)	98.0-102.0%
Water Determination	4.5-8.0%

MAXIMUM LIMITS

Elemental Impurities	As reported
Organic Impurities Test 1:	Acceptance criteria
Pantoprazole Related Compound A	0.20%
Pantoprazole Related Compound B	0.15%
Any Other Individual Impurity	0.10%
Total Impurities	0.5%
OR Organic Impurities Test 2:	Acceptance criteria
Pantoprazole Related Compound C	0.10%
Pantoprazole Related Compound A	0.20%
Pantoprazole Related Compounds D & F	0.20%
Pantoprazole Related Compound E	0.10%
Pantoprazole Related Compound B	0.15%
Any Other Individual Impurity	0.10%
Total Impurities	0.5%
Residual Solvents	To pass test

LIGHT SENSITIVE: Keep in well-closed, light-resistant containers.

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

Spectrum Chemical Mfg Corp

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732.214.1300

West Coast Facility:

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