

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

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.1.5H20
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:		

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:
<i>Pantoprazole Sodium</i>	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
<i>Pantoprazole Sodium</i>	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-phrase(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

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End of Safety Data Sheet