



Pantoprazole sodium sesquihydrate

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 19/08/2015

Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: Pantoprazole sodium sesquihydrate
Chemical name	: 1H-Benzimidazole, 5-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]-sulfinyl]-, sodium salt, hydrate (2:3)
CAS No.	: 164579-32-2
Product code	: PP
Formula	: C ₁₆ H ₁₄ N ₃ NaO ₄ S.1.5H ₂ O
Synonyms	: 5-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridyl)methyl] sulfinyl]benzimidazole, sodium salt, sesquihydrate
Product group	: Pharmaceutical product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	: Industrial use, Professional use
Industrial/Professional use spec.	: Isolated intermediate
Function or use category	: Antiulcerative

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Hetero drugs Ltd
7-2-A2, Hetero Corporate, Industrial Estate
500082 Hyderabad - INDIA
T 04023774009
DRRama@heterodrugs.com - www.heterodrugs.com

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40


Full text of R-phrases: see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)	:	
		None

CLP Signal word	:	Warning
Hazard statements (CLP)	:	H335 - May cause respiratory irritation H332 - Harmful if inhaled H315 - Causes skin irritation H312 - Harmful in contact with skin H302 - Harmful if swallowed
Precautionary statements (CLP)	:	P102 - Keep out of reach of children P103 - Read label before use P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P232 - Protect from moisture P233 - Keep container tightly closed P234 - Keep only in original container

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P235+P410 - Keep cool. Protect from sunlight

EUH phrases

: EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Multi-constituent
Name : Pantoprazole sodium sesquihydrate
CAS No. : 164579-32-2
EC no :
EC index no :

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Acetone	(CAS No.) 67-64-1 (EC no) 200-662-2 (EC index no) 606-001-00-8		F; R11 Xi; R36 R66 R67
Ethanol	(CAS No.) 64-17-5 (EC no) 200-578-6 (EC index no) 603-002-00-5		F; R11
Methanol	(CAS No.) 67-56-1 (EC no) 200-659-6 (EC index no) 603-001-00-X		F; R11 T; R23/24/25-39/23/24/25
Diisopropyl ether	(CAS No.) 108-20-3 (EC no) 203-560-6 (EC index no) 603-045-00-X		F; R11 R19 R66 R67
Dichloromethane	(CAS No.) 75-09-2 (EC no) 200-838-9 (EC index no) 602-004-00-3		Carc.Cat.3; R40
5-(Difluoromethoxy)-1H-benzimidazole-2-thiol	(CAS No.) 97963-62-7		Not classified
5-(Difluoromethoxy)-2-[(RS)-[3,4-dimethoxypyridin-2-yl]methyl]sulfinyl]-1-methyl-1H-benzimidazole	(CAS No.) 624742-53-6		Not classified
6-(Difluoromethoxy)-2-[(RS)-[3,4-dimethoxypyridin-2-yl]methyl]sulfinyl]-1-methyl-1H-benzimidazole	(CAS No.) 624742-53-6		Not classified
5-(difluoromethoxy)-2-[[[3,4-dimethoxy-2-pyridyl)methyl]sulfonyl]-1H-benzimidazole			Not classified
5-(difluoromethoxy)-2-[[[3,4-dimethoxy-2-pyridyl)methyl]thio]-1H-benzimidazole			Not classified
Mixture of the stereo isomers of 6,6'-bis(difluoromethoxy)-2,2'-bis[[[3,4-dimethoxypyridin-2-yl)methyl]sulfinyl]-1H,1'H-5,5'-bibenzimidazolyl			Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Acetone	(CAS No.) 67-64-1 (EC no) 200-662-2 (EC index no) 606-001-00-8		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Ethanol	(CAS No.) 64-17-5 (EC no) 200-578-6 (EC index no) 603-002-00-5		Flam. Liq. 2, H225
Methanol	(CAS No.) 67-56-1 (EC no) 200-659-6 (EC index no) 603-001-00-X		Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
Diisopropyl ether	(CAS No.) 108-20-3 (EC no) 203-560-6 (EC index no) 603-045-00-X		Flam. Liq. 2, H225 STOT SE 3, H336
Dichloromethane	(CAS No.) 75-09-2 (EC no) 200-838-9 (EC index no) 602-004-00-3		Carc. 2, H351
5-(Difluoromethoxy)-1H-benzimidazole-2-thiol	(CAS No.) 97963-62-7		Not classified
5-(Difluoromethoxy)-2-[(RS)-[3,4-dimethoxypyridine-2-yl]methyl]sulphanyl]-1-methyl-1H-benzimidazole	(CAS No.) 624742-53-6		Not classified
6-(Difluoromethoxy)-2-[(RS)-[3,4-dimethoxypyridine-2-yl]methyl]sulphanyl]-1-methyl-1H-benzimidazole	(CAS No.) 624742-53-6		Not classified
5-(difluoromethoxy)-2-[[[3,4-dimethoxypyridin-2-yl)methyl]sulphonyl]-1H-benzimidazole			Not classified
5-(difluoromethoxy)-2-[[[3,4-dimethoxypyridin-2-yl)methyl]sulphanyl]-1H-benzimidazole			Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Mixture of the stereo isomers of 6,6'-bis(difluoromethoxy)-2,2'-bis[[[(3,4-dimethoxypyridin-2-yl)methyl]sulphonyl]-1H,1H'-5,5'-bibenzimidazolyl			Not classified

Full text of R-, H- and EUH-phrases: see section 16.

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. check the vital fuctions-Unconscious:maintain adequate airway andrespiration. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after inhalation	: Immediately wash skin with soap and copious Amounts of waterfor at least 15 minutes. If Irritation persists seek medical attention . Remove the victim into fresh air-Respiratory problems:consult a doctor/medical service. Remove to fresh air and keep patient at rest. Seek medical attention immediately. Rewmove contaminated clothing. Flush arera with large amount of water. USE SOAP. seek medical attention.
First-aid measures after skin contact	: Rewmove contaminated clothing. Flush arera with large amount of water. USE SOAP. seek medical attention. Wash immediately with lots of water-Sope may be used-Do not apply(chemical)neutralizing agents-Take victim to a doctor if irritation persists.
First-aid measures after eye contact	: Immediately flush eyes with running water for at least 15 minutesSeek medical attention. Rinse immediately with lots of water-Do not apply neutralizing agents-Take victim to an ophthalmoglogist if irritation persists. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after ingestion	: If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Rinse mouth with water-Immediately after ingestion:give lots of water to drink. Never give anything by mouth to an unconscious person.Wash out mouth with water.Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use carbon dioxide, dry chemical.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable with air within explosin lomits Indirect fire hazard may be ignited by sparks Gas/vapour spreads at floor level:ignition hazard.
Explosion hazard	: Not expected for the product, although the packaging is combustible.
Reactivity	: Reacts slowly with air-Upon combustion CO and CO2 are formed-And formation of metallic fumes-React with (some)-metals.

5.3. Advice for firefighters

Precautionary measures fire : Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent premiss.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

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6.3. Methods and material for containment and cleaning up

For containment	: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods for cleaning up	: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Other information	: Wash clothing and equipment after handling.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Gloves.
Handling temperature	: 25 °C

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Preserve in tight container at 2-8°C.
Storage temperature	: 2-8 °C
Storage area	: Store away from heat.
Special rules on packaging	: Triple laminated aluminium package.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal protective equipment	: Gloves. Dust production: dust mask with filter type P2. Protective clothing. Protective goggles.



Materials for protective clothing	: Chloroprene rubber nitrile rubber.
Hand protection	: Gloves.
Eye protection	: Protective goggles.
Skin and body protection	: Protective clothing.
Respiratory protection	: Gas mask with filter type A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: White to off-white powder.
Molecular mass	: 432.4
Colour	: White.
Odour	: None.
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Solidification point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available

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Solubility	: Freely soluble in water, in methanol and dehydrate alcohol ,Practically insoluble in hexane and in dichloromethane.
Log Pow	: No data available
Log Kow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts slowly with air-Upon combustion CO and CO₂ are formed-And formation of metallic fumes-Reacts with (some)-metals.

10.2. Chemical stability

Stable under defined conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Freely soluble in water.
Ecology - air	: Not dangerous for the ozone layer(1999/45/EC).

12.2. Persistence and degradability

Pantoprazole sodium sesquihydrate (164579-32-2)	
Persistence and degradability	% biodegradation.

12.3. Bioaccumulative potential

Pantoprazole sodium sesquihydrate (164579-32-2)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.

12.4. Mobility in soil

Pantoprazole sodium sesquihydrate (164579-32-2)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : No other effects known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Additional information : Wash clothing and equipment after handling.

Ecology - waste materials : Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

SECTION 14: Transport information

No dangerous good in sense of transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No Annex XVII restrictions

Contains no REACH candidate substance

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

Full text of R-, H- and EUH-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapour
H301	Toxic if swallowed
H311	Toxic in contact with skin
H319	Causes serious eye irritation
H331	Toxic if inhaled
H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
H370	Causes damage to organs
R11	Highly flammable.
R19	May form explosive peroxides.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R36	Irritating to eyes.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect
R66	Repeated exposure may cause skin dryness or cracking.
R67	Vapours may cause drowsiness and dizziness.
F	Highly flammable
T	Toxic
Xi	Irritant

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.