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-Benimidazole, 5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl]-sulfinyl]-, sodium salt, hydrate (2:3)
CAS No.: 164579-32-2
Product code: PP
Formula: C16H14N3NaO4S.1.5H2O
Synonyms: 5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridyl]methyl] sulfinyl]benzimidazole, sodium salt, sesquihydrate

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
DPRama@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]

CLP Signal word: Warning

Hazard pictograms (CLP): None

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
Pantoprazole sodium sesquihydrate
Safety Data Sheet
according to Regulation (EC) No. 453/2010

EUH phrases
P235+P410 - Keep cool. Protect from sunlight
: EUH210 - Safety data sheet available on request

2.3. Other hazards
No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

<table>
<thead>
<tr>
<th>Substance type</th>
<th>Name</th>
<th>CAS No.</th>
<th>EC no</th>
<th>EC index no</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Directive 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>(CAS No.) 67-64-1</td>
<td></td>
<td>F; R11</td>
</tr>
<tr>
<td>Ethanol</td>
<td>(CAS No.) 64-17-5</td>
<td></td>
<td>F; R11</td>
</tr>
<tr>
<td>Methanol</td>
<td>(CAS No.) 67-56-1</td>
<td></td>
<td>F; R11</td>
</tr>
<tr>
<td>Disopropyl ether</td>
<td>(CAS No.) 108-20-3</td>
<td></td>
<td>F; R11 R19 R66 R67</td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>(CAS No.) 75-09-2</td>
<td></td>
<td>Carc. Cat. 3; R40</td>
</tr>
<tr>
<td>5-(Difluoromethoxy)-1H-benzimidazole-2-thiol</td>
<td>(CAS No.) 97963-62-7</td>
<td></td>
<td>Not classified</td>
</tr>
<tr>
<td>5-(Difluoromethoxy)-2-[(RS)-<a href="methyl">3,4-dimethoxy-2-yl</a>sulfinyl]-1-methyl-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
</tr>
<tr>
<td>6-(Difluoromethoxy)-2-[(RS)-<a href="methyl">3,4-dimethoxy-2-yl</a>sulfinyl]-1-methyl-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
</tr>
<tr>
<td>5-(difluoromethoxy)-2-[(3,4-dimethoxy-2-pyridyl)methyl]sulfonyl]-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
</tr>
<tr>
<td>5-(difluoromethoxy)-2-[][(3,4-dimethoxy-2-pyridyl)methyl][thiol]-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
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<tr>
<td>Mixture of the stereo isomers of 6,6'-bis(difluoromethoxy)-2,2'-bis[(3,4-dimethoxy-2-y1)methyl)sulfinyl]-1H,1H-5,5'-benzimidazolyl</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>(CAS No.) 67-64-1</td>
<td></td>
<td>Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H370</td>
</tr>
<tr>
<td>Ethanol</td>
<td>(CAS No.) 64-17-5</td>
<td></td>
<td>Flam. Liq. 2, H225</td>
</tr>
<tr>
<td>Methanol</td>
<td>(CAS No.) 67-56-1</td>
<td></td>
<td>Flam. Liq. 2, H225 Acute Tox 3 (Dermal), H311 Acute Tox 3 (Inhalation), H331 Acute Tox 3 (Oral), H301 STOT SE 1, H370</td>
</tr>
<tr>
<td>Disopropyl ether</td>
<td>(CAS No.) 108-20-3</td>
<td></td>
<td>Flam. Liq. 2, H225 STOT SE 3, H336</td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>(CAS No.) 75-09-2</td>
<td></td>
<td>Carc. 2, H351</td>
</tr>
<tr>
<td>5-(Difluoromethoxy)-1H-benzimidazole-2-thiol</td>
<td>(CAS No.) 97963-62-7</td>
<td></td>
<td>Not classified</td>
</tr>
<tr>
<td>5-(Difluoromethoxy)-2-[(RS)-<a href="methyl">3,4-dimethoxy-2-yl</a>sulfinyl]-1-methyl-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
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<tr>
<td>6-(Difluoromethoxy)-2-[(RS)-<a href="methyl">3,4-dimethoxy-2-yl</a>sulfinyl]-1-methyl-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
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<td>Not classified</td>
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<tr>
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<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
</tr>
<tr>
<td>5-(difluoromethoxy)-2-[][(3,4-dimethoxy-2-pyridyl)methyl][thiol]-1H-benzimidazole</td>
<td>(CAS No.) 624742-53-6</td>
<td></td>
<td>Not classified</td>
</tr>
</tbody>
</table>
**Pantoprazole sodium sesquihydrate**

**Safety Data Sheet**

according to Regulation (EC) No. 453/2010

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### 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 functions-Unconscious: maintain adequate airway and respiration. 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 water for 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 area with large amount of water. USE SOAP. seek medical attention.

**First-aid measures after skin contact**

Rewmove contaminated clothing. Flush area with large amount of water. USE SOAP. seek medical attention. Wash immediately with lots of water. 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 minutes. Seek medical attention. Rinse immediately with lots of water. Do not apply neutralizing agents. Take victim to an ophthalmologist 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 lormits. 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 - Reacts 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 premis.

**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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Full text of R-, H- and EUH-phrases: see section 16.
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 2-8ºC.
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.


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
Solubility : Freely soluble in water, in methanol and dehydrate alcohol, Practically insoluble in hexane and in dichlomethane.

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.

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.
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 clothiong and equipment after handling.
Ecology - waste materials : Take up liquid spil 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:

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

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.