

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: PANTOPRAZOLE SODIUM SESQUIHYDRATE
Chemical name	: Sodium-5-difluoromethoxy-2-((3,4-dimethoxy-2-pyridinylmethyl)-sulfinyl) -1Hbenzimidazole sesquihydrate
IUPAC name	: Sodium-5-difluoromethoxy-2-((3,4-dimethoxy-2-pyridinylmethyl)-sulfinyl) -1Hbenzimidazole sesquihydrate
CAS-No.	: 164579-32-2
Product code	: 76420
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C32H34F4N6Na2O11S2
Synonyms	: Pantoprazole sodium sesquihydrate ; 1H-Benzimidazole,6-(difluoromethoxy)-2-[[[(3, / 4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-, sodiumsalt, hydrate (2:2:3)
Other means of identification	: SMILES:COc1ccnc(c1OC)CS(=O)c2[n-]c3ccc(cc3n2)OC(F)F.COc1ccnc(c1OC)CS(=O)c2[n-]c3ccc(cc3n2)OC(F)F.O.O.O.[Na+].[Na+]

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API,Industrial use,Professional use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: Anti-ulcer agents. Anti-Infective agents. Enzyme Inhibitors. Proton-pump Inhibitors.
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Supplier**

MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer

MOEHS CANTABRA, S.L.
Pol. Ind. Requejada
39313 Polanco
Spain
T +34 942 131 045 - F +34 942 82 43 98
hse@moehs.com

1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (oral), Category 4	H302
Skin sensitisation, Category 1	H317
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. May cause sensitisation of susceptible persons. May irritate eyes and skin.

PANTOPRAZOLE SODIUM SESQUIHYDRATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H317 - May cause an allergic skin reaction.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear eye protection, protective gloves, face protection, protective clothing.
P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P330 - Rinse mouth.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%
PANTOPRAZOLE SODIUM SESQUIHYDRATE	CAS-No.: 164579-32-2	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell. Allow affected person to breathe fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Wash contaminated clothing before reuse. Wash with plenty of water/.... If skin irritation occurs: Get medical advice/attention. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects	: If you feel unwell, seek medical advice.
Symptoms/effects after inhalation	: May cause respiratory irritation. May cause an allergic skin reaction.
Symptoms/effects after skin contact	: May irritate eyes and skin. May cause sensitisation of susceptible persons by skin contact.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: Swallowing a small quantity of this material will result in serious health hazard.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
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6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep away from ignition sources. Store at room temperature. Keep container closed when not in use. Keep only in the original container in a cool, well ventilated place away from :
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m³)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Dust extraction (suction). Breathing equipment. Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Safety glasses. Gloves. Dust/aerosol mask. Protective clothing. Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Wear protective gloves.

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Hand protection		
Type	Material	Standard
Disposable gloves	Polyvinylalcohol (PVA), Polyvinylchloride (PVC), Fluoroelastomer (FKM), Neoprene rubber (HNBR), Latex	EN ISO 374

Other skin protection Materials for protective clothing		
Condition	Material	Standard
Good resistance:	Tyvek®, Polyethylene, Polyethylene/ethylenevinylalcohol, Synthetic material, Latex	EN 13034, EN 1149-1, EN 14126, EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask, Full face mask, Powered hoods/helmets, Powered Air-Purifying Respirator (PAPR)	Type P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: Dust.
Molecular mass	: 864.75 g/mol [Pantoprazole sodium sesquihydrate]
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 130 °C [Pantoprazole; Predicted by ACDLabs]
Freezing point	: Not available
Boiling point	: 586.9 [Pantoprazole; at 760 mmHg; Predicted by ACDLabs]
Flammability	: Dust could form explosive mixtures with air
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 308.7 °C [Pantoprazole; Predicted by ACDLabs]
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable

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Solubility	: Soluble in water. Water: 0.026 g/l [Pantoprazole; pH=6.39 (25°C); predicted by ACD/Labs]
Partition coefficient n-octanol/water (Log Kow)	: 2.22 [Pantoprazole; KOWWIN v1.67 est]
Partition coefficient n-octanol/water (Log Pow)	: 0.506 – 2.636 [Pantoprazole; 25°C; Predicted by ACD/Labs]
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy	: > 1000 mJ
Additional information	: Dust Cloud minimum Flammability Temperature : 530°C. Layer Minimum flammability Temperature : >400°C. Explosion Severity Factor Kmax (bar.m/s) : 152. Explosion Class : St1

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

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PANTOPRAZOLE SODIUM SESQUIHYDRATE (164579-32-2)	
LD50 oral rat	747 mg/kg [Pantoprazole sodium]
LD50, oral, mouse	>1000 mg/kg [Pantoprazole sodium]
LD50, intravenous, rat	256 mg/kg [Pantoprazole sodium]
LD50, intravenous, mouse	395 mg/kg [Pantoprazole sodium]

Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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11.2.2. Other information

Potential adverse human health effects and symptoms	: Harmful if swallowed.
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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

12.2. Persistence and degradability

PANTOPRAZOLE SODIUM SESQUIHYDRATE (164579-32-2)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

PANTOPRAZOLE SODIUM SESQUIHYDRATE (164579-32-2)	
BCF - Fish [1]	10.3 [Pantoprazole; Predicted by BCFWIN v2.17]
Partition coefficient n-octanol/water (Log Pow)	0.506 – 2.636 [Pantoprazole; 25°C; Predicted by ACD/Labs]
Partition coefficient n-octanol/water (Log Kow)	2.22 [Pantoprazole; KOWWIN v1.67 est]

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PANTOPRAZOLE SODIUM SESQUIHYDRATE (164579-32-2)

Bioaccumulative potential : Not established.

12.4. Mobility in soil

PANTOPRAZOLE SODIUM SESQUIHYDRATE (164579-32-2)

Organic Carbon Normalized Adsorption Coefficient (Log Koc) : ≈ 4.125 [Pantoprazole; Predicted by PCKOCWIN v1.66]

12.5. Results of PBT and vPvB assessment

PANTOPRAZOLE SODIUM SESQUIHYDRATE (164579-32-2)

vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Additional information : Industrial waste.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

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IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

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PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed
SZW-lijst van mutagene stoffen : The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
IARC	International Agency for Research on Cancer
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IATA	International Air Transport Association

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Abbreviations and acronyms:	
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

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.