



(+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI-HYDRATE (PYRIDYL-4-METHOXY-13C, 98%)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 06/09/2012

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Supersedes: 01/03/2013

Version: 3.0

CLM-7831

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

1.1. Product identifier

Product form : Substance
Substance name : (+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI- HYDRATE (PYRIDYL-4-METHOXY-13C, 98%)
CAS-No. : 138786-67-1 (Unlabeled)
Product code : CLM-7831
Formula : C15*CH14F2N3O4SNa·1.5H2O

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

1.2.1. Relevant identified uses

Main use category : Professional use
Industrial/Professional use spec : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Cambridge Isotope Laboratories, Inc.
50 Frontage Road
Andover, MA 01810
USA

USA: 1-800-322-1174 Int: 1-978-749-8000
cilsales@isotope.com www.isotope.com

Emergency telephone number

Emergency numbers:

Chemtrec: 1-800-424-9300 (24 hours)
International: 1-703-741-5970 (24 hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute Tox. 4 (Oral) H302
Skin Irrit. 2 H315
Eye Irrit. 2 H319
Carc. 2 H351
STOT SE 3 H335

Full text of hazard classes and H-statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Xi; R36/37/38
Xn; R22/R40

Full text of R-phrases: see section 16

GHS-US classification

Acute Tox. 4 (Oral) H302
Skin Irrit. 2 H315
Eye Irrit. 2 H319
Carc. 2 H351
STOT SE 3 H335

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Respiratory system, lungs.

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2.2. Label elements

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

Hazard pictograms (CLP)



GHS08

GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H351 - Suspected of causing cancer

Precautionary statements (CLP)

: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: Call a doctor, a POISON CENTER if you feel unwell.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

GHS-US labeling

Hazard pictograms (GHS-US)



GHS08

GHS07

Signal word (GHS-US)

: Warning

Hazard statements (GHS-US)

: H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H351 - Suspected of causing cancer

Precautionary statements (GHS-US)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - If swallowed: Call a doctor if you feel unwell
P302+P352 - If on skin: Wash with plenty of water
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313 - If exposed or concerned: Get medical advice/attention.
P312 - Call a doctor, a POISON CENTER if you feel unwell
P321 - Specific treatment (see Hazardous component(s) for labeling on this label)
P330 - Rinse mouth.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

(+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI- HYDRATE (PYRIDYL-4-METHOXY-13C, 98%)

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Name	Product identifier	%	Classification according to Directive 67/548/EEC
(+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI- HYDRATE (PYRIDYL-4-METHOXY-13C, 98%)	(CAS-No.) 138786-67-1 (Unlabeled)	100	Xi; R36/37/38 Xn; R22/R40

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
(+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI- HYDRATE (PYRIDYL-4-METHOXY-13C, 98%)	(CAS-No.) 138786-67-1 (Unlabeled)	100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Carc. 2, H351 STOT SE 3, H335

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

Name	Product identifier	%	GHS-US classification
(+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI- HYDRATE (PYRIDYL-4-METHOXY-13C, 98%) (Main constituent)	(CAS-No.) 138786-67-1 (Unlabeled)	100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Carc. 2, H351 STOT SE 3, H335

Full text of H-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	: If you feel unwell, seek medical advice (show the label where possible). Evacuate danger area.
First-aid measures after inhalation	: When symptoms occur: go into open air and ventilate suspected area. If not breathing give artificial respiration. Get medical advice/attention.
First-aid measures after skin contact	: Wash with plenty of soap and water. and soap. Get immediate medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes.
First-aid measures after ingestion	: Never give anything by mouth to an unconscious person. Rinse mouth out with water. Get medical advice/attention.

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

Symptoms/effects after inhalation	: May be harmful if inhaled. May cause respiratory tract irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Harmful if swallowed.
Chronic symptoms	: Suspected carcinogen.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray, dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions	: Fight fire with normal precautions from a reasonable distance. Wear a self contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection. Wear recommended personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid breathing vapors, mist, gas. Avoid dust formation.

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6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent entry to sewers and public waters. Do not allow to enter drains or water courses. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal.
Methods for cleaning up : This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide adequate ventilation to minimize dust and/or vapor concentrations.
Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Store in a well-ventilated place. Keep container tightly closed.
Storage conditions : Store at room temperature away from light and moisture.

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 : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
Personal protective equipment : Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.



Materials for protective clothing : Wear suitable protective clothing and gloves.
Hand protection : Wear suitable protective clothing and gloves.
Eye protection : Wear eye protection. Chemical goggles or face shield with safety glasses.
Skin and body protection : Wear suitable protective clothing, gloves and eye/face protection.
Respiratory protection : In case of inadequate ventilation wear respiratory protection. Approved supplied air respirator.
Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Powder
Molecular mass : 433.4 g/mol (Labeled)
Color : White
Odor : No data available
Odor threshold : No data available
pH : 10.05 (1%)
Relative evaporation rate (butyl acetate=1) : No data available
Melting point : 130 °C
Freezing point : No data available
Boiling point : No data available
Flash point : No data available

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Auto-ignition temperature	: No data available
Decomposition temperature	: 137.5 °C
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble.
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Five years after receipt if stored as stated in "Storage" section. Re-QC after 5 years.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Extremes of temperature and direct sunlight.

10.5. Incompatible materials

Strong oxidizing agents. Strong acids.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides. Hydrogen fluoride. Sodium oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

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LD50 oral rat	747 - 900 mg/kg
ATE CLP (oral)	500.000 mg/kg body weight

Skin corrosion/irritation	: Causes skin irritation. pH: 10.05 (1%)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 10.05 (1%)
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: Not classified
Specific target organ toxicity – single exposure	: May cause respiratory irritation.
Specific target organ toxicity – repeated exposure	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: 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. Metabolism and nutrition disorders. Gastrointestinal disorders. Exposure may produce an allergic reaction

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Symptoms/effects after inhalation	: May be harmful if inhaled. May cause respiratory tract irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Harmful if swallowed.
Chronic symptoms	: Suspected carcinogen.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

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LC50 fish 1	45.97 mg/l - 96h
EC50 Daphnia 2	50.75 mg/l - 48h
ErC50 (algae)	> 34.8 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Waste materials should be disposed of under conditions which meet Federal, State, and local environmental control regulations.
Product/Packaging disposal recommendations	: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.
Ecology - waste materials	: Dispose of as unused product.

SECTION 14: Transport information

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

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Additional information

Other information : No supplementary information available.

Overland transport

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

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14.4. Environmental hazards

Other information : No supplementary information available.

14.5. Special precautions for user

14.6. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

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SARA Section 302 Threshold Planning Quantity (TPQ)	Not subject to reporting requirements of the United States SARA Section 302.
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
SARA Section 313 - Emission Reporting	Not subject to reporting requirements of the United States SARA Section 313.

15.2. International regulations

CANADA

(+/-)-PANTOPRAZOLE, SODIUM SALT: SESQUI- HYDRATE (PYRIDYL-4-METHOXY-13C, 98%) (138786-67-1 (Unlabeled))

Listed on the Canadian DSL (Domestic Substances List)

15.2.1. National regulations

No additional information available

15.3. US State regulations

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U.S. - California - Proposition 65 - Carcinogens List	No
U.S. - California - Proposition 65 - Developmental Toxicity	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Female	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No
State or local regulations	U.S. - Pennsylvania - RTK (Right to Know) List U.S. - New Jersey - Right to Know Hazardous Substance List

SECTION 16: Other information

Other information : This product is not radioactive. The data given for this product are those of the corresponding unlabeled compound, unless specifically indicated otherwise. Health and safety data for labeled compounds are generally not available, but are assumed to be similar or identical to the corresponding unlabeled compound.

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

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H351	Suspected of causing cancer
R22	Harmful if swallowed
R36/37/38	Irritating to eyes, respiratory system and skin
Xi	Irritant
Xn	Harmful

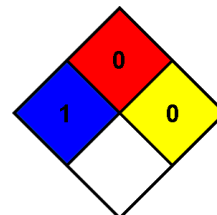
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NFPA health hazard	: 1 - Materials that, under emergency conditions, can cause significant irritation.
NFPA fire hazard	: 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.
NFPA reactivity	: 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health	: 1 Slight Hazard - Irritation or minor reversible injury possible
Flammability	: 0 Minimal Hazard
Physical	: 0 Minimal Hazard

CIL Substance SDS

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