

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

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Publication: 12/04/2022

Revision: XX/XX/XXXX

Version: 00



## THIAMINI HYDROCHLORIDUM

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Thiamine hydrochloride Thiamini hydrochloridum Thiamine hydrochloride Thiamine (chlorhydrate de) Thiamin Hydrochlorid
N° CAS:	67-03-8
N° EC:	200-641-8

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

#### 2.3 Other hazards

Not available (PBT, vPvB, Substance is an endocrine disruptor etc.)

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Thiamine hydrochloride
IUPAC name:	3-[(4-Amino-2-methylpyrimidin-5-yl)methyl]-5-(2-hydroxyethyl)-4-methyl-1,3-thiazol-3-ium chloride hydrochloride
Synonyms:	Vitamin B <sub>1</sub> Aneurine hydrochloride
N° CAS:	67-03-8
N° EC:	200-641-8
Molecular Formula:	C <sub>12</sub> H <sub>18</sub> Cl <sub>2</sub> N <sub>4</sub> OS
Content:	98.5 per cent to 101.0 per cent (anhydrous substance)

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	In all cases of doubt, or when symptoms persist, seek medical attention.
After inhalation:	Remove from exposure to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid if cough or other symptoms appear.
After skin contact:	Flush skin with plenty of soap and water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.
After eye contact:	Immediately flush thoroughly with water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid immediately.
After ingestion:	Get medical aid immediately. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cups of milk or water.

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

The material is not expected to be harmful.

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

As a precaution, get medical advice/attention. Treat symptomatically and supportively.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Use dry chemical sandy soil, chemical foam, carbon dioxide.
Unsuitable extinguishing media:	Not available.

#### 5.2 Special hazards arising from the substance/mixture

Emits toxic fumes under fire conditions.

#### 5.3 Advice for firefighters

Surrounding fires:	Not available.
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Protection against fire:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products:

Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Remove ignition sources. Provide adequate ventilation. Avoid inhalation of dust. Avoid skin and eye contact. Wear protective gloves/protective clothing/eye protection/face protection.

##### For emergency responders

Wear an appropriate NIOSH/MSHA approved respirator if mist, vapour or dust is generated.

#### 6.2 Environmental precautions

Avoid disposing into drainage/sewer system or directly into the aquatic environment. Keep away from drains, surface and ground water and soil.

#### 6.3 Methods and material for containment and cleaning up

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

In case of small amount, wash with water. In case of large amount, cover with non-flammable material and recover.

#### 6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information on personal protective equipment.

See section 13 for information on disposal.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:

Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation. Avoid prolonged, or repeated, skin contact.

Personal protection:

Not available.

Technical protective measures:

Minimise dust generation and accumulation. Use with adequate ventilation.

Handling:

Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Wash clothing before reuse.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

In a non-metallic container.

Conditions for safe storage, including any incompatibilities:

Keep container closed when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances. Store in well-closed containers at a temperature < 40 °C, preferably between 15-30 °C.

Storage – away from:

Store protected from light. Store away from incompatible substances.

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### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Occupational exposure limits: Not listed.

Additional exposure limits under the conditions of use: Not available.

DNEL/DMEL and PNEC-values: Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Facilities storing or utilising this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

#### Individual protection measures

Eye/face protection: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN 166.

Skin protection: Wear appropriate protective clothing to minimise contact with skin.

Hand protection: Wear appropriate protective gloves to prevent skin exposure.

Respiratory protection: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

Thermal hazards: Wear appropriate protective clothing to minimise contact with skin.

#### Environmental exposure control

According to local regulations, federal and official regulations.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder or colourless crystals.

Odour: Odourless.

Odour threshold: Not available.

pH: 2.7 – 3.3 (25 g/l)

Melting/freezing point: Approx. 248 °C (with decomposition)

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not applicable.

Flammability (solid/gas): Not flammable.

Upper/lower flammability or explosive limits: Not determined.

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Vapour pressure:	Not determined.
Vapour density:	Not applicable.
Relative density:	Not determined.
Solubility:	Soluble in glycerol. Slightly soluble in ethanol (96 per cent). Practically insoluble in heptane.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not determined.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Approx. 248 °C
Viscosity:	Not determined.
Explosive properties:	Not determined.
Oxidising properties:	Not applicable.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

The substance does not react vigorously with reducing agent, so it does not belong to oxidising substances.

### 10.2 Chemical stability

Under normal conditions, the product is stable. No hazardous reaction when handled and stored according to provisions. Hazardous reactions are not known.

### 10.3 Possibility of hazardous reactions

Under normal conditions, no hazardous reactions will occur.

### 10.4 Conditions to avoid

Incompatible materials, light, dust generation, excess heat, strong oxidants, moisture.

### 10.5 Incompatible materials

Oxidising agent and reducing agents, alkalis and metal.

### 10.6 Hazardous decomposition products

Carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub> ...), sulfur oxides (SO<sub>2</sub>, SO<sub>3</sub> ...), halogenated compounds.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): 3.71 g/kg
Skin corrosion/irritation:	Not irritating.
Serious eye damage/irritation:	Not irritating.
Respiratory/skin sensitisation:	Not sensitising.
Germ cell mutagenicity:	Not classified.

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Carcinogenicity:	Not classified.
Reproductive toxicity:	Not classified.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified.
STOT-repeated exposure:	Not classified.
Aspiration Hazard:	Not classified.
Other:	Not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Acute toxicity	Time	Species	Method
LC <sub>50</sub> > 100 mg/l	96 h	Fish ( <i>Oncorhynchus mykiss</i> )	OECD 203
EC <sub>50</sub> > 100 mg/l	48 h	<i>Daphnia magna</i>	OECD 202
EC <sub>50</sub> > 100 mg/l	72 h	<i>Scenedesmus subspicatus</i>	OECD 201

### 12.2 Persistence and degradability

There is high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the biodegradation activity of activated sludge is not anticipated when introduces biological treatment plants in appropriate low concentrations.

#### Elimination information

Test method:	OECD 302B, activated sludge
Method of analysis:	DOC reduction
Degree of elimination:	74 % (7d)
Evaluation:	Biodegradable. Readily eliminated from water.

### 12.3 Bioaccumulative potential

Accumulation in organisms is not to be expected.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not applicable.

### 12.6 Other adverse effects

Not applicable.

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Waste treatment methods: Material does not have an EPA Waste Number and is not a listed waste, however consultation with a permitted waste disposal site (TSD) should be accomplished. Always contact a permitted waste disposal to assure compliance with all current local, state and federal regulations. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. According to local regulations, federal and official regulations.

Product/packaging disposal: If empty container retains product residues, all label precautions must be observed. Return for reuse or dispose according to national or local regulations.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not regulated.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not regulated.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not regulated.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not regulated.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not regulated.

##### 14.6 Special precautions for user

See section 2.2.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

##### 14.8 Additional transport information

Not available.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

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### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.  
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available.

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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