

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/10

Publication: 26/04/2022

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## PHENYLEPHRINI HYDROCHLORIDUM

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

#### 1.1 Product identifier

|               |   |
|---------------|---|
| Product name: | Phenylephrine hydrochloride<br>Phenylephrini hydrochloridum<br>Fenylefrine hydrochloride<br>Phényléphrine (chlorhydrate de)<br>Phenylephrinhydrochlorid |
| N° CAS:       | 61-76-7   |
| N° EC:        | 200-517-3   |

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

|                  |  |
|------------------|--|
| Identified uses: | Active Pharmaceutical Ingredient or Excipient. |
|------------------|--|

#### 1.3 Details of the supplier of the safety data sheet

|            |   |
|------------|---|
| Company:   | FAC SECUNDUM ARTEM NV<br>Oostmalsebaan 1c (unit 5)<br>2960 Sint-Lenaarts<br>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

|               |      |
|---------------|------|
| Acute Tox. 4  | H302 |
| Skin Irrit. 2 | H315 |
| Eye Irrit. 3  | H319 |
| STOT SE 3     | H335 |

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

|                                       |  |
|---------------------------------------|--|
| H302                                  | Harmful if swallowed.  |
| H315                                  | Causes skin irritation.  |
| H319                                  | Causes serious eye irritation.   |
| H335                                  | May cause respiratory irritation.  |
| Precautionary statements:             |  |
| P261                                  | Avoid breathing dust.  |
| P264                                  | Wash skin thoroughly after handling.   |
| P270                                  | Do not eat, drink, or smoke when using this product.   |
| P271                                  | Use only outdoors or in well-ventilated area.  |
| P280                                  | Wear protective gloves/eye protection/face protection.   |
| P301+P312                             | IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.  |
| P302+P352                             | IF ON SKIN: Wash with plenty of water.   |
| P304+P340                             | IN INHALED: Remove victim to fresh air and keep at rest in a position 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. |
| P312                                  | Call a POISON CENTER or doctor/physician if you feel unwell.   |
| P321                                  | Specific treatment (see supplemental first aid instructions 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 well-ventilated place. Keep container tightly closed.   |
| P405                                  | Store locked up.   |
| P501                                  | Dispose of contents/container to an approved waste disposal plant.   |
| Additional applicable label elements: | Not applicable.  |

### 2.3 Other hazards

See section 4.2.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

|               |  |
|---------------|--|
| Product name: | Phenylephrine hydrochloride  |
| IUPAC name:   | (1R)-1-(3-Hydroxyphenyl)-2-(methylamino)ethanol hydrochloride.               |
| Synonyms:     | M-Synephrine Hydrochloride<br>Metaoxedrine chloride<br>Adrianol<br>Biomydrin |
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# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

Molecular Formula:  $C_9H_{14}ClNO_2$   
Content: 98.5 per cent to 101.0 per cent (dried substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

**General notes:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

**After inhalation:** Causes irritation and is absorbed by this route. Avoid inhalation. Remove to fresh air.

**After skin contact:** Causes irritation and may be absorbed from this route. Flush with copious quantities of soap and water for at least 15 minutes.

**After eye contact:** Causes irritation and is absorbed by this route. Avoid eye contact. Flush with copious quantities of water for at least 15 minutes.

**After ingestion:** May cause irritation, bitter taste, and toxicity. Flush out mouth with water. This material is irregularly absorbed from the gastrointestinal tract.

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

**Adverse effects:** Adverse effects may include headache, nausea or vomiting, anxiety, seizures, hallucinations, increased sweating, abnormal behaviour, palpitations, pain in eye, mild skin rash or itching, burning sensation, mild stomach pain, trouble urinating, fever, fainting, unusual bleeding, nasal congestion, tremor, chest pain, change in heart rate, difficulty breathing, and restlessness. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

**Overdose effects:** Symptoms of overdose include irregular heartbeat, tingling in the extremities, sensation of fullness in the head, and severe increase in blood pressure.

**Acute:** Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

**Chronic:** Possible hypersensitisation.

**Medical conditions aggravated by exposure:** Hypersensitivity to material, heart problems, high blood pressure, asthma, diabetes mellitus, thyroid disease, and pheochromocytoma.

**Target organs:** Smooth muscle, brain, and cardiovascular system.

For additional information on toxicity, see section 11.

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

Note to physicians: Overdose Treatment: Most overdoses require only patient observation because phenylephrine has a very short duration of action. If overdose causes an excessive hypertensive effect, a short-acting alpha-adrenergic blocker, such as phentolamine 5 to 10 mg intravenously, may be used.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media: Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

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

Not available.

### 5.3 Advice for firefighters

|                                |   |
|--------------------------------|---|
| Surrounding fires:             | As with all fires, evacuate personnel to a safe area.   |
| Protection against fire:       | Firefighters should use self-contained breathing equipment and protective clothing.             |
| Hazardous combustion products: | Carbon monoxide, carbon dioxide, nitrogen oxide, hydrochloric acid, irritating and toxic fumes. |

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Avoid breathing dust.

#### For emergency responders

Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Avoid breathing dust.

### 6.2 Environmental precautions

Not available.

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

Spill response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

|                                |  |
|--------------------------------|--|
| Precautions for safe handling: | Keep containers closed tightly when not in use. Minimize dust generation and accumulation. Avoid contact with skin, eyes and clothing. Avoid prolonged or repeated exposure. Protect against physical damage. Empty containers may contain product residue. Do not damage empty container. |
| Personal protection:           | Not available.   |
| Technical protective measures: | Not available.   |
| Handling:                      | Wash hands with soap and water after contact.  |

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

|   |   |
|---|---|
| Storage:  | Store in suitable, labelled container.  |
| Conditions for safe storage, including any incompatibilities: | Store in dry, room temperature, well ventilated area. Consumption of food and beverage should be avoided in work area. Wash hands with soap and water thoroughly before eating, drinking. Keep away |

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

Storage – away from:

incompatible substances, such as oxidizing agents, acids, acid chlorides, acid anhydrides, hydrogen chloride gas, nitrogen oxides.

Keep away incompatible substances, such as oxidizing agents, acids, acid chlorides, acid anhydrides, hydrogen chloride gas, nitrogen oxides.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Keep workroom concentration below current applicable OSHA safety and health requirements.

If necessary, configure the explosion-proof, anti-static devices.

Eye washer and safely shower if needed.

#### Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Lab coat.

Hand protection: Protective gloves.

Respiratory protection: Appropriate vapour canister, self-contained breathing apparatus or supplied-air hose mask below current applicable OSHA safety and health requirements.

Thermal hazards: Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: Neutral (aqueous solution)

Melting/freezing point: About 143 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: < 1

Flammability (solid/gas): Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

|   |  |
|---|--|
| Upper/lower flammability or explosive limits: | Not available.                           |
| Vapour pressure:                              | Not available.                           |
| Vapour density:                               | Not available.                           |
| Relative density:                             | Not available.                           |
| Solubility:                                   | Freely soluble in ethanol (96 per cent). |
| Solubility in water:                          | Freely soluble in water.                 |
| Partition coefficient (n-octanol/water):      | -0.31                                    |
| Auto-ignition temperature:                    | 480 °C                                   |
| Decomposition temperature:                    | Not available.                           |
| Viscosity:                                    | Not available.                           |
| Explosive properties:                         | Not available.                           |
| Oxidising properties:                         | Not available.                           |

### 9.2 Other information

Molecular weight: 203.67 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable.

Hazardous polymerization: No.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Avoid exposure to light.

### 10.5 Incompatible materials

Strong oxidizing agents, acids, acid chlorides, and acid anhydrides.

### 10.6 Hazardous decomposition products

When heated to decomposition, material emits very toxic fumes of HCl and NO<sub>x</sub>.

Emits toxic fumes under fire conditions.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

|                 |   |
|-----------------|---|
| Acute toxicity: | Oral LD <sub>50</sub> (rat): 350 mg/kg.           |
|                 | Intraperitoneal LD <sub>50</sub> (rat): 17 mg/kg. |
|                 | Subcutaneous LD <sub>50</sub> (rat): 27 mg/kg.    |

# Material Safety Data Sheet

EN

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

FORM-06-14-01 (V00)

Page 7/10

## PHENYLEPHRINI HYDROCHLORIDUM

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



|  |  |
|--|--|
|  | Intravenous LD <sub>50</sub> (rat): 440 mg/kg.   |
|  | Oral LD <sub>50</sub> (mouse): 120 mg/kg.  |
|  | Intraperitoneal LD <sub>50</sub> (mouse): 89 mg/kg.  |
|  | Subcutaneous LD <sub>50</sub> (mouse): 22 mg/kg.   |
|  | Intravenous LD <sub>50</sub> (mouse): 1120 µg/kg.  |
|  | Subcutaneous LD <sub>50</sub> (rabbit): 22 mg/kg.  |
|  | Intravenous LD <sub>50</sub> (rabbit): 500 µg/kg.  |
|  | Intramuscular LD <sub>50</sub> (rabbit): 7200 µg/kg.   |
| Skin corrosion/irritation:                   | Not available.   |
| Serious eye damage/irritation:               | Not available.   |
| Respiratory/skin sensitisation:              | Not available.   |
| Germ cell mutagenicity:                      | Phenylephrine hydrochloride was positive in the mouse lymphoma L5178Y test, without metabolic activation. It was not mutagenic in the S. typhimurium test, with and without metabolic activation. Phenylephrine hydrochloride induced sister-chromatid exchanges but not chromosomal aberrations in Chinese hamster ovary cells, without metabolic activation. |
| Carcinogenicity:                             | Not listed as a carcinogen by NTP, ICRC and OSHA.  |
| Reproductive toxicity:                       | Phenylephrine may cause vasoconstriction of uterine blood vessels and the reduction of uterine blood flow, resulting in foetal hypoxia.  |
| Summary of evaluation of the CMR properties: | Not available.   |
| STOT-single exposure:                        | Not available.   |
| STOT-repeated exposure:                      | Not available.   |
| Aspiration Hazard:                           | Not available.   |
| Other:                                       | Not available.   |

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

|               |                                   |
|---------------|-----------------------------------|
| Eye contact:  | Causes serious eye irritation.    |
| Skin contact: | Causes skin irritation.           |
| Inhalation:   | May cause respiratory irritation. |
| Ingestion:    | Harmful if swallowed.             |
| Aspiration:   | Not available.                    |

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

All disposals must comply with federal, state, and local regulation. The material, if spilled or discarded, may be a regulated waste. Refer to state and local regulations. If regulated solvents are used to clean up spilled material, the resulting waste mixture may be regulated.

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

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

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

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

#### 14.6 Special precautions for user

Not available.

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

Not available.

#### 14.8 Additional transport information

Packaging information: Cardboard barrels.  
It is considered non-dangerous goods by ICAO, IATA, IMDG.

## SECTION 15: REGULATORY INFORMATION



# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

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

Hazard symbol:



Irritant

Risk phrases:

R22 Harmful if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

S7 Keep container tightly closed.

S22 Do not breathe dust.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36 Wear suitable protective clothing.

S46 If swallowed, seek medical advice immediately and show this container or label.

### 15.2 Chemical safety assessment

Not available.

## 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

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 10/10

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENYLEPHRINI HYDROCHLORIDUM

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

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