

# Material Safety Data Sheet

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

## PROMETHAZINI HYDROCHLORIDUM

EN

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

#### 1.1 Product identifier

Product name:	Promethazine hydrochloride Promethazini hydrochloridum Promethazinehydrochloride Prométhazine (chlorhydrate de) Prometazinhydrochlorid
N° CAS:	58-33-3
N° EC:	200-375-2

#### 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

Acute Tox. 4	H302
Acute Tox. 4	H332
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Skin Sens. 1	H317
STOT SE 3	H335
Aquatic Chronic 2	H411

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s):

Attention

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### Hazard statements:

H302+H332	Harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long-lasting effects.

### Precautionary statements:

P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P321	Specific treatment (see on this label).
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P362	Take off contaminated clothing.
P501	Dispose of this substance and its container to a special or hazardous waste collection point in accordance with local, regional, national and/or international regulations.

Additional applicable label elements: Not applicable.

### 2.3 Other hazards

None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Promethazine hydrochloride
IUPAC name:	<i>N,N</i> -dimethyl-1-phenothiazin-10-ylpropan-2-amine hydrochloride
Synonyms:	Phenergan Diprazin
N° CAS:	58-33-3
N° EC:	200-375-2
Molecular Formula:	C <sub>17</sub> H <sub>21</sub> ClN <sub>2</sub> S
Content:	99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.

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After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

Blurred vision, dizziness, rash, nausea and vomiting.

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

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water fog. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

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

In case of fire, fumes harmful to health may be produced: carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), sulphur oxides (SO<sub>x</sub>) and hydrogen chloride (HCl).

### 5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

For exposure control and personal protective measures, see section 8. Avoid breathing vapours. Ensure adequate ventilation.

#### For emergency responders

For exposure control and personal protective measures, see section 8. Avoid breathing vapours. Ensure adequate ventilation.

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### 6.2 Environmental precautions

- Prevent release to the environment.
- Prevent entry into sewers and watercourses.
- If product enters drains or public waterways, notify authorities.

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

- Store away from other materials.
- If on the ground, sweep or scoop (shovel or similar) into suitable containers.
- Limit dust production.

### 6.4 Reference to other sections

- For exposure control and personal protective measures, see section 8.
- For waste disposal, follow the recommendations in section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

- |                                |   |
|--------------------------------|---|
| Precautions for safe handling: | Obtain special instructions before use. Do not eat, drink or smoke while handling this product. Avoid breathing dust, fumes, gas, mist, vapours or spray. |
| Personal protection:           | Not available.  |
| Technical protective measures: | Ensure good ventilation of the processing area to avoid vapour formation.   |
| Handling:                      | Wash thoroughly after handling.   |

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

- |   |   |
|---|---|
| Storage:  | Not available.  |
| Conditions for safe storage, including any incompatibilities: | Store in a cool place. Keep container tightly closed in a dry and well-ventilated place. Keep container closed when not in use. |
| Storage – away from:  | Store protected from light.   |

### 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

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

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### Individual protection measures

Eye/face protection:	Protective face shields and safety goggles according to EN166.
Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
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 faintly yellowish, crystalline powder.
Odour:	Odourless
Odour threshold:	Not available.
pH:	4.0 to 5.0
Melting/freezing point:	About 222 °C, with decomposition
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
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) and in methylene chloride.
Solubility in water:	Very soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

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### 9.2 Other information

Molecular weight: 320.89 g/mol

Density (20 °C): 0.398 g/ml

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

### 10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

### 10.3 Possibility of hazardous reactions

None known.

### 10.4 Conditions to avoid

Direct sunlight. Extremely high or extremely low temperatures. Humidity.

### 10.5 Incompatible materials

Strong oxidizing agents.

### 10.6 Hazardous decomposition products

In case of fire, fumes harmful to health may be produced: carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), sulphur oxides (SO<sub>x</sub>) and hydrogen chloride (HCl).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (mouse): 255 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	May cause skin sensitisation.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	May impair fertility.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause respiratory irritation.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and Symptoms of Exposure: Blurred vision, dizziness, rash, nausea and vomiting. N° RTECS: SO8225000

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

Eye contact: May cause serious eye irritation.

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Skin contact:	Harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

EC<sub>50</sub> (fish): 2 mg/L/96 hours

EC<sub>50</sub> (aquatic invertebrates): 1.5 mg/L/48 hours (*Daphnia magna*)

#### 12.2 Persistence and degradability

Non-biodegradable product (2 %).

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

#### 12.6 Other adverse effects

Avoid release to the environment. Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

### 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) : 2811

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (PROMETHAZINE HYDROCHLORIDE)  
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (PROMETHAZINE HYDROCHLORIDE)  
IATA: TOXIC SOLID, ORGANIC, N.O.S. (PROMETHAZINE HYDROCHLORIDE)

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### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : 6.1

### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : II

### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not hazardous for the environment.

### 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

The product is classified according to the hazardous materials conventions.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Harmful to the environment

Risk phrases:

R20/22 Harmful by inhalation and if swallowed.

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

R43 May cause sensitisation by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

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

S27 Take off immediately all contaminated clothing.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S56 Dispose of this material and its container at hazardous or special waste collection point.

### 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.



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### 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  
[info@magis-pharma.be](mailto:info@magis-pharma.be)

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