

## MORPHINUM HYDROCHLORIDUM

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

#### 1.1 Product identifier

Product name:	Morphine hydrochloride Morphinum hydrochloridum Morfine hydrochloride Morphine (chlorhydrate de) Morphinhydrochlorid
N° CAS:	52-26-6
N° EC:	200-136-2

#### 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:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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. 3	H311
Eye Irrit. 2	H319
Acute Tox. 3	H331
STOT SE 3	H336
Repr. 2	H361
Repr. 2	H361fd
Lact.	H362

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s):

Danger

Hazard statements:

H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H319	Causes serious eye damage.
H331	Toxic if inhaled.
H336	May cause drowsiness or dizziness.
H361	Suspected of damaging fertility or the unborn child.
H361fd	Suspected of damaging fertility; Suspected of damaging the unborn child.
H362	May cause harm to breast-fed children.

Precautionary statements:

P203	Obtain, read and follow all safety instructions before use.
P233	Keep container tightly closed.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P262	Do not get in eyes, on skin, or on clothing.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284	[In case of inadequate ventilation] Wear respiratory protection.
P301+P316	If swallowed: Get emergency medical help immediately.
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.
P318	If exposed or concerned, get medical advice.
P330	Rinse mouth.
P332+P317	If skin irritation occurs: Get emergency medical help.
P337+P317	If eye irritation persists: Get emergency medical help.
P342+P316	If experiencing respiratory symptoms: Get emergency medical help immediately.
P361+P364	Take off immediately all contaminated clothing. And wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
	Dispose of contents/container to local/regional/national/international regulations.

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P501

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Morphine hydrochloride
IUPAC name:	(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7,9-diol;hydrochloride
Synonyms:	Thebametten Morphine chlorhydrate Epimore Morphinum muriaticum Morphinan-3,6- $\alpha$ -diol, 7,8-didehydro-4,5- $\alpha$ -epoxy-17-methyl-, hydrochloride Morphine Hydrochloride Salt
N° CAS:	52-26-6
N° EC:	200-136-2
Molecular Formula:	C <sub>17</sub> H <sub>20</sub> ClNO <sub>3</sub>
Content:	98.0 % to 102.0 % (anhydrous substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Not applicable.
After inhalation:	In case of accident, move to an open air area, transport urgently to hospital and seek advice from the toxicological information center.
After skin contact:	Immediately wash with plenty of water and immediately take off all contaminated clothing. Transport the affected person to hospital and seek advice from the toxicological information center.
After eye contact:	Rinse immediately with plenty of water and consult a specialist. Transport the affected person to hospital and seek advice from the toxicological information center.

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After ingestion:

In case of accident, rinse the mouth with plenty of water, transport the affected person to hospital and seek advice from the toxicological information center.

Self-protection of the first aider:

Not applicable.

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

Regardless of exposure route, it can cause acute symptoms of irritation in the exposed area.

Effects of overdose: confusion, convulsion, severe dizziness, severe drowsiness, weakness, nervousness, agitation, low blood pressure, low frequency of pulsations, slow or difficult breathing and unconsciousness.

Harmful if swallowed.

Absorption of this product may cause drowsiness, made worse by alcoholic drinks or certain medicines.

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

Call a physician immediately. Oxygen administration may be necessary. There are antidotes for opiates, for example naloxone.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:

Water spray, foam, dry powder, CO<sub>2</sub>.

Unsuitable extinguishing media:

High pressure water jet as it disperses the product.

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

In case of combustion or heating to decomposition it may emit nitric (NO<sub>x</sub>) and chlorine (HCl) vapours, which are toxic.

### 5.3 Advice for firefighters

Surrounding fires:

Not available.

Protection against fire:

Self-contained breathing apparatus and protective clothing.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Intervene with appropriate personal protective equipment.

- Respiratory protection with dust filter.

- Eyes: glasses.

- Hands: gloves of suitable material.

- Body: complete combination.

- In case of dust emissions (grinding): respiratory apparatus with free or compressed air intake.

#### For emergency responders

Intervene with appropriate personal protective equipment.

- Respiratory protection with dust filter.

- Eyes: glasses.

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- Hands: gloves of suitable material.
- Body: complete combination.
- In case of dust emissions (grinding): respiratory apparatus with free or compressed air intake.

### 6.2 Environmental precautions

Contain the spillage, prevent from reaching the environment.

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

Avoid raising dust, recover the entire product and place it in a tightly closed and labelled container. After completing material recovery, ventilate the area and wash with plenty of water.

### 6.4 Reference to other sections

Not applicable.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Air extraction in the workstation: Under all circumstances avoid inhalation (aerosol) and all contact with eyes and skin.

Other measures: As with all powdered products avoid the accumulation of electrostatic charges by using the appropriate materials and methods. Handle in a facility specific to narcotics.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Not available.

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

Storage:

Store protected from light. Store under lock and key.

Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Not available.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Occupational exposure limits values not available.

NOAEL = 0.001675 mg/kg\*

OEL= 0.01175 µg/m<sup>3</sup>

\*Data calculated using NTP 724: Drugs in the pharmaceutical industry (IV): guide values for occupational exposure, National Institute of Occupational Safety and Health, based on the substance's LD50 of the substance, always applying the principle of worst case scenario.

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### 8.2 Exposure controls

#### Appropriate engineering control

Product related measures to prevent exposure: In case of dust emission (grinding): breathing apparatus with free compressed air intake.

#### Individual protection measures

Eye/face protection:	Eyes: glasses.
Skin protection:	Body: complete combination.
Hand protection:	Hands: gloves of suitable material.
Respiratory protection:	Respiratory protection with dust filter.
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 or colourless, silky needles or cubical masses, efflorescent in a dry atmosphere.
Odour:	Not available.
Odour threshold:	Not available.
pH:	4.5 – 5.5 (2 % aqueous solution. 20 °C)
Melting/freezing point:	Not available.
Initial boiling point:	200 °C (after drying at 80 °C)
Boiling range:	200 °C (after drying at 80 °C)
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:	Soluble in water, slightly soluble in ethanol (96 %), practically insoluble in toluene.
Solubility in water:	Soluble in water.
Partition coefficient (n-octanol/water):	Log Kow = 0.66
Auto-ignition temperature:	Not available.

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Decomposition temperature: Not available.  
Viscosity: Not available.  
Explosive properties: Not explosive.  
Oxidising properties: Not oxidizing.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not reactive under normal conditions.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

In case of combustion or heating to decomposition it may emit nitric (NO<sub>x</sub>) and chlorine (HCl) vapours, which are toxic.

### 10.4 Conditions to avoid

Thermal decomposition: product stable under normal conditions of use.  
Exposed material loses hydration water.  
Protect from light, as the product is sensitive to light and can degrade if exposed to it.

### 10.5 Incompatible materials

Oxidising agents and alkaline compounds.

### 10.6 Hazardous decomposition products

In case of combustion or heating to decomposition it may emit nitric (NO<sub>x</sub>) and chlorine (HCl) vapours, which are toxic.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: LD<sub>50</sub> (Mouse Oral Ret.): 335 mg/kg (dry product) according to Ph.Eur.  
LD<sub>50</sub> (Mouse Oral Ret.): 226-318 mg/kg (dry product) according to the Merck Index.  
Harmful if swallowed.

Skin corrosion/irritation: Not classified as irritant according to Regulation CLP 1272.

Serious eye damage/irritation: Not classified as eye irritant according to Regulation CLP 1272.

Respiratory/skin sensitisation: Not classified as sensitising according to Regulation CLP 1272.

Germ cell mutagenicity: Not classified as mutagenic according to Regulation CLP 1272.

Carcinogenicity: Not classified as carcinogenic according to regulation CLP 1272.

Reproductive toxicity: Not classified as toxic for reproduction according to regulation CLP 1272.

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Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Classified as target toxicity in certain organs due to category 3 exposure, narcotic effects.
STOT-repeated exposure:	Not classified as specifically toxic for organs according to regulation CLP 1272.
Aspiration Hazard:	Not classified as aspiration hazard under CLP 1272.
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

Not available.

### 12.2 Persistence and degradability

Photolysis-susceptible.

### 12.3 Bioaccumulative potential

Based on Kow, low bioaccumulation potential is expected.

### 12.4 Mobility in soil

Based on Kow, low mobility is expected.

### 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

Proper disposal / product: Do not dispose of product to the environment. Collect and store separately.  
Additional information Destroy in accordance with the regulations on narcotics. Follow current local and national regulations.

## SECTION 14: TRANSPORT INFORMATION

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



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<b>14.1 UN Number</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	UN 1544
<b>14.2 UN proper shipping name</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Solid alkaloids N.O.S., Solid salt alkaloids N.O.S.
<b>14.3 Transport hazard class(es)</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Class: 6.1 Classification: T2
<b>14.4 Packing group</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	III
<b>14.5 Environmental hazards</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
<b>14.6 Special precautions for user</b>	
Not available.	
<b>14.7 Transport in bulk according to annex II of Marpol and the IBC Code</b>	
Not available.	
<b>14.8 Additional transport information</b>	
Not available.	
<b>SECTION 15: REGULATORY INFORMATION</b>	
<b>15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture</b>	
Hazard symbol:	Not applicable.
Risk phrases:	Not applicable.
Safety phrases:	Not applicable.
<b>15.2 Chemical safety assessment</b>	
Not available.	
<b>SECTION 16: OTHER INFORMATION</b>	
<b>16.1 Changes since the previous version</b>	
Not applicable.	
<b>16.2 Abbreviations and acronyms used</b>	
ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road

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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

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