

# Material Safety Data Sheet

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

## METHADONI HYDROCHLORIDUM

EN

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

#### 1.1 Product identifier

Product name:	Methadone hydrochloride Methadoni hydrochloridum Methadon hydrochloride Méthadone (chlorhydrate de) Methadonhydrochlorid
N° CAS:	1095-90-5
N° EC:	214-140-7

#### 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 toxicity (category 3)	H301
Skin irritation (category 2)	H315
Eye irritation (category 2)	H319
Aquatic chronic (category 2)	H411

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

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### Hazard statements:

H301	Toxic if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H411	Toxic to aquatic life with long lasting effects

### Precautionary statements:

P260	Do not breath dust
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Additional applicable label elements:



### 2.3 Other hazards

Physical-, chemical and toxicological hazards:

- May be toxic by inhalation or in contact with skin
- May be irritating to respiratory system
- May cause some adverse effects on fertility
- May cause some adverse effects to the unborn child
- May cause some adverse effects on breastfeed babies
- Dust may be explosive (no data available)

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Methadone hydrochloride
IUPAC name:	6-(dimethylamino)-4,4-diphenylheptan-3-one hydrochloride
Synonyms:	Not applicable
N° CAS:	1095-90-5
N° EC:	214-140-7
Molecular Formula:	C <sub>21</sub> H <sub>28</sub> ClNO
Content:	99.0% – 101.0% (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Take the victim out of the contaminated area. Remove contaminated clothing immediately and dispose of safely.
After inhalation:	Move to fresh air. Make the victim blow his nose. Seek medical advice.
After skin contact:	Rinse immediately with plenty of water for at least 15 minutes. Seek medical advice.
After eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical advice immediately.

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After ingestion: Do not induce vomiting. Make the victim rinse his mouth with water. Seek medical advice immediately.

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

Constipation, nausea and vomiting, and drowsiness.

### 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: All means (e.g. water, carbon dioxide, dry chemical extinguisher).

Unsuitable extinguishing media: Strong water jet.

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

In case of fire, the product may emit toxic and/or irritating fumes. Supposed thermal decomposition/oxidation: Carbon monoxide and carbon dioxide, Nitrogen oxides (NOx) and Hydrogen chloride (HCl).

### 5.3 Advice for firefighters

Surrounding fires: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Avoid rejection of extinguishing water in the environment.

Protection against fire: Use self-contained breathing apparatus. Wear full protective suit.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Particle full face respirator or powered air purifying respirator. Suitable gloves. Dedicated work clothes.

#### For emergency responders

Particle full face respirator or powered air purifying respirator. Suitable gloves. Dedicated work clothes.

### 6.2 Environmental precautions

Avoid any spreading of the product.

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

General advice: Sweep and shovel the solid product in a container adapted for its recovery or destroying (avoiding dust formation). Close and label rigorously.

Cleaning of contaminated zone: After taking up the product, rinse the polluted area with water.

Elimination of recovered materials: Deliver to Environmental service of the factory or to any specialized and approved disposal service.

### 6.4 Reference to other sections

Additional advice: Evacuation of area and intervention of special services recommended.

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### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Local ventilation and emission point dust extraction. Enclosed transfer recommended.
Personal protection:	Handling in a hood.
Technical protective measures:	Take precautionary measures against electrostatic loading. Earth vessels and equipment well.
Handling:	Handling in a hood.

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

Storage:	Keep in a cool, well-ventilated place. Advised packaging material: Glass, polyethylene and polypropylene.
Conditions for safe storage, including any incompatibilities:	Keep away from chemicals as it is a pharmaceutical substance. Keep in a well closed container, away from moisture and light. Keep at room temperature (15-25°C).
Storage – away from:	The product is sensitive to light and to moisture.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Concentration limits in air: OEL-8h (internal): 10 µg/m<sup>3</sup>

#### 8.2 Exposure controls

##### Appropriate engineering control

Pregnant women: seek medical advice before handling. Warning drivers of machines on risks of drowsiness.

##### Individual protection measures

Eye/face protection:	See respiratory protection.
Skin protection:	Working clothes.
Hand protection:	Suitable gloves. Wash hands
Respiratory protection:	Particle full face mask or powered air purifying respirator or handling in a hood.
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, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.

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pH:	4.5 – 6.5 at 10 g/L (20 °C).
Melting/freezing point:	233 °C – 236 °C.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
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 alcohols and chloroform.
Solubility in water:	Easily soluble in water (120 g/L).
Partition coefficient (n-octanol/water):	Log P: 1.4 (computed value QSAR)
Auto-ignition temperature:	> 270 °C
Decomposition temperature:	From 200 °C
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Dust may be explosive (no data available).

### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidizing agents.

### 10.6 Hazardous decomposition products

Supposed thermal decomposition/oxidation: Carbon monoxide and carbon dioxide, Nitrogen oxides (NOx) and Hydrogen chloride (HCl).

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### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50: 30 – 95 mg/kg (species: rat).
Skin corrosion/irritation:	Irritating to skin.
Serious eye damage/irritation:	Irritating to eyes.
Respiratory/skin sensitisation:	Non sensitizing (Method: Local Lymph Node Assay (LLNA)).
Germ cell mutagenicity:	Considered non genotoxic.
Carcinogenicity:	No carcinogenic effects in animals.
Reproductive toxicity:	May cause some adverse effects on fertility. Some reprotoxic effects have been observed in animals. Some risk of neonatal effects. Discouraged during breastfeeding.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Substance pharmacologically active. Opioid analgesic. Narcotic. Antitussive.

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

Eye contact:	Irritating to eyes.
Skin contact:	Irritating to skin.
Inhalation:	Not available.
Ingestion:	Constipation, nausea and vomiting, and drowsiness.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Fish toxicity LC50: 33.2 mg/L (Species: Danio rerio (zebra fish), exposure duration: 96 h).  
Toxicity on invertebrates EC50: 7.7 mg/L (Species: Daphnia magna (water flea), exposure duration: 48 h).  
Bacteria toxicity EC50: 287 mg/L (Species: activated sludge, exposure duration: 3 h).

#### 12.2 Persistence and degradability

Biological degradability < 10% (Testing period: 28 d).  
The product is not readily biodegradable according to OECD criteria.

#### 12.3 Bioaccumulative potential

Unlikely to be bioaccumulable in living organisms (Log P < 4)

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

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### 12.6 Other adverse effects

Note: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Do not release material and cleaning waters into the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Product: Deliver to the Environmental service of the factory or to any specialized and approved disposal service.

Uncleaned packaging: Deliver to the Environmental service of the factory or to any specialized and approved disposal service.

## 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) : UN2811

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : ADR: 2811 TOXIC SOLID, ORGANIC, N.O.S. (Methadone hydrochloride),  
ENVIRONMENTALLY HAZARDOUS  
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (Methadone Hydrochloride), MARINE  
POLLUTANT  
IATA: TOXIC SOLID, ORGANIC, N.O.S. (Methadone Hydrochloride)

#### 14.3 Transport hazard class(es)

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



Class 6.1: Toxic substances, label 6.1

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Environmentally hazardous substance, solid; Marine Pollutant

#### 14.6 Special precautions for user

Warning: Toxic substances.

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

Not applicable.

#### 14.8 Additional transport information

Special marking with the symbol (fish and tree).

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### SECTION 15: REGULATORY INFORMATION

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

Not applicable.

#### 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

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

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