

# Material Safety Data Sheet

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

## MECLOZINI DIHYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

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

#### 1.1 Product identifier

Product name:	Meclozine dihydrochloride Meclozini dihydrochloridum Meclozine dihydrochloride Méclozine (dichlorhydrate de) Meclozindihydrochlorid
N° CAS:	1104-22-9
N° EC:	214-164-8

#### 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.centreatipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

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

Acute Tox. 4	H302
Repr. 2	H361

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302	Harmful if swallowed.
H361	Suspected of damaging fertility or the unborn child.

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### Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash thoroughly after handling.
P281	Use personal protective equipment as required.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P330	Rinse mouth.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Meclozine dihydrochloride
IUPAC name:	1-[(4-chlorophenyl)-phenylmethyl]-4-[(3-methylbenzyl)methyl]piperazine dihydrochloride
Synonyms:	Meclizine dihydrochloride Bonamine
N° CAS:	1104-22-9
N° EC:	214-164-8
Molecular Formula:	C <sub>25</sub> H <sub>29</sub> Cl <sub>3</sub> N <sub>2</sub>
Content:	98.0 per cent to 102.0 per cent (anhydrous substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
After skin contact:	Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
After eye contact:	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
After ingestion:	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

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

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Harmful if swallowed.

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation or skin absorption.

May cause eye, skin, or respiratory system irritation.

Suspected of damaging fertility or the unborn child.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

### 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: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Unsuitable extinguishing media: A solid water stream may be inefficient.

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

Not available.

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear 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

Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

#### For emergency responders

Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

### 6.2 Environmental precautions

Take steps to avoid release into the environment, if safe to do so.

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

Contain spill and collect, as appropriate.

Transfer to a chemical waste container for disposal in accordance with local regulations.

### 6.4 Reference to other sections

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Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
Technical protective measures:	Not available.
Handling:	Not available.

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

Storage:	In an airtight container. Store in accordance with information listed on the product insert.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed.
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

Not available.

#### 8.2 Exposure controls

##### Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Work/hygienic/maintenance practices: Do not take internally. Facilities storing or utilising this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling.

##### Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Lab coat.
Hand protection:	Compatible chemical-resistant gloves.
Respiratory protection:	NIOSH approved respirator, as conditions warrant.
Thermal hazards:	Not determined.

##### Environmental exposure control

Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

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## MECLOZINI DIHYDROCHLORIDUM

Appearance:	White or yellowish-white, slightly hygroscopic, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
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:	Soluble in ethanol (96 per cent) and in methylene chloride.
Solubility in water:	Slightly 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.

### 9.2 Other information

Molecular weight: 481.89 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable if stored in accordance with information listed on the product insert.

Polymerisation: Will not occur.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

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Strong oxidising agents.

### 10.6 Hazardous decomposition products

Carbon dioxide, carbon monoxide, hydrogen chloride, nitrogen oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (mouse): 1 600 mg/kg Intraperitoneal LD50 (mouse): 625 mg/kg Oral TDLO (rat): 800 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	The toxicological effects of this product have not been thoroughly studied. Chronic toxicological effects: Investigated as a drug and reproductive effector. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. RTECS number: TL2005000

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

Eye contact:	May cause eye irritation.
Skin contact:	May be harmful by skin absorption. May cause skin irritation.
Inhalation:	Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation. May cause respiratory system irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Avoid release into the environment.  
Runoff from fire control or dilution water may cause pollution.

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### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 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

Dispose in accordance with local, state, and federal 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 classified.

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

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

#### 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

Transport in accordance with local, state, and federal regulations.

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### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful

Risk phrases:

R22 Harmful if swallowed.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases:

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

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S53 Avoid exposure – obtain special instructions before use.

#### 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.



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### 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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