

MIDAZOLAMI HYDROCHLORIDUM

Publication: 19/09/2024  
Revision: XX/XX/XXXX  
Version: 00

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

1.1 PRODUCT IDENTIFIER

Product name: EN: Midazolam hydrochloride  
LAT: Midazolami hydrochloridum  
NL: Midazolamhydrochloride  
FR: Midazolam (chlorhydrate de)  
DE: Midazolamhydrochlorid  
N° CAS: 59467-96-8  
N° EC: 261-776-6

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE/MIXTURE AND USES ADVISED AGAINST

Identified uses: Active Pharmaceutical Ingredient.

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
STOT SE 3	H336
Repr. 2	H361
Lact.	H362

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning  
Danger

Hazard statements:  
H302 Harmful if swallowed.

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H336	May cause drowsiness or dizziness.
H361	Suspected of damaging fertility or the unborn child.
H362	May cause harm to breast-fed children.
Precautionary statements:	
P203	Obtain, read and follow all safety instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash face, hands and any exposed skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P317	IF SWALLOWED: Get medical help.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P318	If exposed or concerned, get medical advice.
P319	Get medical help if you feel unwell.
P330	Rinse mouth.
P403+P233	Store in a 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

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

This product does not contain any known or suspected endocrine disruptors.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 SUBSTANCES

Product name:	Midazolam hydrochloride
IUPAC name:	8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine;hydrochloride
Synonyms:	Hypnovel Versed Rocam
N° CAS:	59467-96-8
N° EC:	261-776-6
Molecular Formula:	C <sub>18</sub> H <sub>14</sub> Cl <sub>2</sub> FN <sub>3</sub>
Content:	100%

### 3.2 MIXTURES

Not applicable.

## SECTION 4: FIRST AID MEASURES

### MAGIS-PHARMA NV

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**4.1 DESCRIPTION OF FIRST AID MEASURES**

General notes:	Show this safety data sheet to the doctor in attendance.
After inhalation:	Remove to fresh air. IF exposed or concerned: Get medical advice/attention.
After skin contact:	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
After eye contact:	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
After ingestion:	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.

**4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**

Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

**4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED**

Treat symptomatically.

**SECTION 5: FIREFIGHTING MEASURES**

**5.1 EXTINGUISHING MEDIA**

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Large fire: CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media:	Do not scatter spilled material with high pressure water streams.

**5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE**

Not available.

**5.3 ADVICE FOR FIREFIGHTERS**

Surrounding fires:	Use personal protection equipment.
Protection against fire:	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
Hazardous combustion products:	Not available.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES**

**FOR NON-EMERGENCY PERSONNEL**

Personal precautions: Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

Other information: Refer to protective measures listed in sections 7 and 8.

**FOR EMERGENCY RESPONDERS**

Use personal protection recommended in section 8.

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**6.2 ENVIRONMENTAL PRECAUTIONS**

See section 12 for additional ecological information.

**6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP**

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

**6.4 REFERENCE TO OTHER SECTIONS**

See section 8 for more information. See section 13 for more information.

**SECTION 7: HANDLING AND STORAGE**

**7.1 PRECAUTIONS FOR SAFE HANDLING**

Precautions for safe handling:

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Personal protection:

Not available.

Technical protective measures:

Ensure adequate ventilation. Avoid breathing vapours or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

Handling:

General hygiene considerations: Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

**7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES**

Storage:

Store only in the original receptacle unless other advice is given on the CoA.

Conditions for safe storage, including any incompatibilities:

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.

Storage – away from:

Protected from light.

**7.3 SPECIFIC END USE(S)**

Active Pharmaceutical Ingredient.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 CONTROL PARAMETERS**

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### Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

### Biological occupational exposure limits

Chemical name	Latvia	Luxembourg	Romania	Slovakia
Midazolam hydrochloride 59467-96-8	-	-	5 mg/g Creatinine – urine (Fluorine) – end of shift	-

**Derived No Effect Level (DNEL):** No information available.

**Predicted No Effect Concentration (PNEC):** No information available.

## 8.2 EXPOSURE CONTROLS

### APPROPRIATE ENGINEERING CONTROL

General hygiene considerations: Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

### INDIVIDUAL PROTECTION MEASURES

Eye/face protection:	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).
Skin protection:	Wear suitable protective clothing.
Hand protection:	Wear suitable gloves. The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves.
Respiratory protection:	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
Thermal hazards:	Not determined.

### ENVIRONMENTAL EXPOSURE CONTROL

Do not allow into any sewer, on the ground or into any body of water.

## 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:	3.7 – 4.7
Melting/freezing point:	159 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.

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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:	Slightly soluble in hydrochlorid acid (0.1 M) and in ethanol (96%).
Solubility in water:	Not available.
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: 362.25

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Not available.

10.2 CHEMICAL STABILITY

**Stability** Stable under normal conditions.

**Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

None under normal processing.

10.4 CONDITIONS TO AVOID

None known based on information supplied.

10.5 INCOMPATIBLE MATERIALS

None known based on information supplied.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

None known based on information supplied.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: Oral LD<sub>50</sub> (rat): 1600 mg/kg (Midazolam hydrochloride)

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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:	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause drowsiness or dizziness.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Symptoms: Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

### 11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

Eye contact:	Specific test data for the substance or mixture is not available.
Skin contact:	Specific test data for the substance or mixture is not available.
Inhalation:	May cause drowsiness or dizziness.
Ingestion:	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).
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.

### 12.4 MOBILITY IN SOIL

Not available.

### 12.5 RESULTS OF PBT AND VPVB ASSESSMENT

Not available.

### 12.6 OTHER ADVERSE EFFECTS

Water hazard class (WGK): Slightly hazardous to water (WGK 1).

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 WASTE TREATMENT METHODS

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Waste from residues/unused products: Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging: Do not reuse empty containers.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN NUMBER

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

14.2 UN PROPER SHIPPING NAME

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

14.3 TRANSPORT HAZARD CLASS(ES)

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

14.4 PACKING GROUP

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

14.5 ENVIRONMENTAL HAZARDS

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

14.6 SPECIAL PRECAUTIONS FOR USER

None.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not available.

14.8 ADDITIONAL TRANSPORT INFORMATION

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE/MIXTURE

Hazard symbol:



Risk phrases:

Irritant, harmful  
R22 Harmful if swallowed.  
R62 Possible risk of impaired fertility.  
R63 Possible risk of harm to the unborn child.  
R64 May cause harm to breastfed babies.

Safety phrases:

S1 Keep locked up.  
S7/9 Keep container tightly closed and in a well-ventilated place.

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S20/21 When using do not eat, drink or smoke.  
S23 Do not breathe gas/fumes/vapour/spray.  
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.  
S46 If swallowed, seek medical advice immediately and show this container or label.  
S51 Use only in well-ventilated areas.  
S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.  
S64 If swallowed, rinse mouth with water (only if the person is conscious).

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

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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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the Magis-Pharma NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. Magis-Pharma NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

**16.8 DEPARTMENT ISSUING MSDS**

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