

Trade name: Midazolamum hydrochloridum

Substance number: 065670

Version: 2 / CH

Date revised: 17.12.2018

Replaces Version: 1 / CH

Print date: 01.10.19

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Midazolamum hydrochloridum

Item No. 06567000

Registration no.

EC No.: 261-776-6

CAS No. 59467-96-8

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4	H302
Repr. 2	H361fd
Lact.	H362
STOT SE 3	H336

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H362	May cause harm to breast-fed children.
H302	Harmful if swallowed.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H336	May cause drowsiness or dizziness.

Precautionary statements

Trade name: Midazolamum hydrochloridum

Substance number: 065670

Version: 2 / CH

Date revised: 17.12.2018

Replaces Version: 1 / CH

Print date: 01.10.19

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy and while nursing.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308+P313	IF expoed or concerned: Get medicinal advice/attention.

Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine monohydrochloride

SECTION 3: Composition/information on ingredients**Hazardous ingredients****8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine monohydrochloride**

CAS No. 59467-96-8

EINECS no. 261-776-6

Registration no. NA

Concentration >= 80 %

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302

STOT SE 3 H336

Repr. 2 H361

Lact. H362

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

If you feel unwell, seek medical advice (show the label where possible).

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

Remove contaminated, soaked clothing immediately and dispose of safely. Wash off with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). By continuous complaints consult a physician.

After ingestion

Let plenty of water be drunk in small gulps. Induce the patient to vomit of his own accord only if fully conscious. Summon a doctor immediately.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Compatible with all usual extinguishing media.

Non suitable extinguishing media

Extinguishing measures to suit surroundings

5.2. Special hazards arising from the substance or mixture

Trade name: Midazolamum hydrochloridum

Substance number: 065670

Version: 2 / CH

Date revised: 17.12.2018

Replaces Version: 1 / CH

Print date: 01.10.19

The product is combustible. In case of combustion evolution of dangerous gases possible. Hydrogen halide

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use personal protective clothing. Use self-contained breathing apparatus.

Other information

Do not discharge into surface waters/groundwater. Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing. Avoid dust formation. Avoid breathing dust. Women of childbearing age should avoid the contact with the product.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

To pick up dry. When picked up, treat material as prescribed under Section 13 "Disposal".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear protective equipment. For personal protection see Section 8.

7.2. Conditions for safe storage, including any incompatibilities

Recommended storage temperature

Value	15	25	°C
-------	----	----	----

Hints on storage assembly

Not required.

Further information on storage conditions

Keep container tightly closed, cool and dry. Protect from light.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

General protective and hygiene measures

Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work. Women of childbearing age should avoid the contact with the product.

Respiratory protection

Breathing apparatus in the event of aerosol. At intensive and longer exposition use self-contained breathing apparatus.

Hand protection

Protective gloves	
Appropriate Material	Natural Latex
Appropriate Material	rubber

Eye protection

Safety glasses with side protection shield

Trade name: Midazolamum hydrochloridum

Substance number: 065670

Version: 2 / CH

Date revised: 17.12.2018

Replaces Version: 1 / CH

Print date: 01.10.19

Body protection

Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Form	Powder
Colour	white to slightly yellow
Odour	odourless
Melting point	
Value	148 to 151 °C
Initial boiling point and boiling range	
Remarks	not determined
Flash point	
Value	°C
Remarks	Not applicable
Solubility in water	
Remarks	virtually insoluble
Solubility(ies)	
Methanol	
Remarks	soluble
Ethanol	
Remarks	soluble

SECTION 10: Stability and reactivity**10.1. Reactivity**

No dangerous reactions known.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

Protect from warmth. Protect from light and atmospheric moisture.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

In the event of fire the following can be released: Toxic gases/vapours

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute oral toxicity**

ATE	1'600	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)

8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine monohydrochloride	
Species	rat

Trade name: Midazolamum hydrochloridum

Substance number: 065670

Version: 2 / CH

Date revised: 17.12.2018

Replaces Version: 1 / CH

Print date: 01.10.19

LD50 1600 mg/kg
Source Midazolam

Skin corrosion/irritation (Components)

8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine monohydrochloride
evaluation slightly irritant

Serious eye damage/irritation (Components)

8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine monohydrochloride
evaluation slightly irritant

Experience in practice

disorders of the central nervous system. Irritating to skin.

SECTION 12: Ecological information**12.1. Toxicity****General information**

For this subsection there is no ecotoxicological data available on the product as such. Do not allow it to reach ground water, water bodies or sewage system.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

EWC waste code 07 05 wastes from the MFSU of pharmaceuticals

Disposal recommendations for packaging

Disposal in compliance with local and national regulations.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	Non-dangerous goods	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Water Hazard Class (Germany)**

Water Hazard Class WGK 1
(Germany)
Remarks Self-assessment

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.
H336 May cause drowsiness or dizziness.
H361 Suspected of damaging fertility or the unborn child.
H362 May cause harm to breast-fed children.

Trade name: Midazolamum hydrochloridum

Substance number: 065670

Version: 2 / CH

Date revised: 17.12.2018

Replaces Version: 1 / CH

Print date: 01.10.19

CLP categories listed in Chapter 3

Acute Tox. 4

Acute toxicity, Category 4

Lact.

Reproductive toxicity, Lactation

Repr. 2

Reproductive toxicity, Category 2

STOT SE 3

Specific target organ toxicity - single exposure, Category 3

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.