

Trade name: Midazolamum

Substance number: 065680 Version: 2 / CH Date revised: 16.02.12

Replaces Version: 1 / CH Date of printing: 14.08.12

# 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Midazolamum

Item-No. 06568000

## 1.2. Relevant identified uses of the substance or mixture and uses advised against

## Use of the substance/preparation

Manufacture of pharmacutical products

#### 1.3. Details of the supplier of the safety data sheet

#### **Address**

Hänseler AG Industriestrasse 35 9101 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

# 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 H30

#### Classification in accordance with EC directives

Classification Xn, R22

#### 2.2. Label elements

### Labelling according to regulation (EC) No 1272/2008

#### Hazard pictograms \*\*\*



## Signal Word \*\*\*

Warning

#### Hazard statements \*\*\*

H302 Harmful if swallowed.

#### **Precautionary statements**

P264.1 Wash hands thoroughly after handling.

P270 Do no eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

#### Labelling in accordance with EC directives 1999/45/EC and 67/548/EEC

The product is classified and labelled in accordance with EC directives/the relevant national laws.



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#### **Hazard symbols**



Harmful

## R phrases

22 Harmful if swallowed.

S phrases \*\*\*

Wear suitable protective clothing.

46 If swallowed, seek medical advice immediately and show this container or label.

This material and its container must be disposed of as hazardous waste.

#### Hazardous component(s) to be indicated on label

contains \*\*\* midazolam

# 3. Composition/information on ingredients \*\*\*

## Hazardous ingredients \*\*\*

#### midazolam

CAS No. 59467-70-8 EINECS no. 261-774-5

Concentration

>= 50 %

Classification Xn, R22

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

Acute Tox. 4 H302

## 4. First aid measures

### 4.1. Description of first aid measures

#### **General information**

Remove affected person from danger area. Take affected person to fresh air. Seek medical advice immediately. In any case show the physician the Safety Data Sheet.

#### After inhalation

Remove affected person from danger area. Remove the casualty into fresh air and keep him calm. Summon a doctor immediately.

#### After skin contact

Remove contaminated, soaked clothing immediately and dispose of safely. Wash off immediately with soap and water and rinse well. Summon a doctor immediately.

### After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Eye treatment by an Occulist.

#### After ingestion

Rinse mouth thoroughly with water. If swallowed, rinse mouth with water (only if the person is conscious). Call in a physician immediately and show him the Safety Data Sheet.

# 5. Firefighting measures

## 5.1. Extinguishing media



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#### Suitable extinguishing media

Water spray jet, Foam, Dry powder, Carbon dioxide

#### 5.2. Special hazards arising from the substance or mixture

The product is combustible. In case of combustion evolution of dangerous gases possible. In the event of fire the following can be released: Nitrous gases (NOx); Carbon monoxide (CO); Carbon dioxide (CO2); compounds containing: Chlorine (Cl2)

#### 5.3. Advice for firefighters

## Special protective equipment for fire-fighting

Use self-contained breathing apparatus.

#### Other information

Cool endangered containers with water spray jet.

## 6. Accidental release measures

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

Wear protective equipment. Refer to protective measures listed in sections 7 and 8.

## 6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

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

Pick up mechanically. When picked up, treat material as prescribed under heading "Disposal". Clean up affected area.

#### 6.4. Reference to other sections

Information regarding personal protective measures see, chapter 8. Information regarding Waste Disposal, see chapter 13.

# 7. Handling and storage

#### 7.1. Precautions for safe handling

#### Advice on safe handling

Wear protective equipment. Keep away sources of ignition.

### Advice on protection against fire and explosion

Keep away from sources of heat and ignition.

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

#### Recommended storage temperature

Value 40 ℃

#### Requirements for storage rooms and vessels

Keep container tightly closed and dry.

## Hints on storage assembly

Not required.

## Further information on storage conditions

Protect from light. Keep container tightly closed in a well-ventilated place.

# 8. Exposure controls/personal protection

#### 8.2. Exposure controls

General protective and hygiene measures



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Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work. Do not eat, drink or smoke during work time. Remove contaminated, soaked clothing immediately and dispose of safely.

## **Respiratory protection**

Dust mask

### **Hand protection**

Protective gloves

Appropriate Material Polyethylene

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated

location

Appropriate Material rubber

## Eye protection

Safety glasses

# 9. Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

**Form** Powder

**Colour** white to slightly yellow

рΗ

Remarks Not determined

**Melting point** 

Value appr. 159 ℃

**Boiling point** 

Remarks Not determined

Solubility in water

Remarks virtually insoluble

Solubility in other solvents

Methanol

Remarks soluble

Ethanol

Remarks soluble

### Octanol/water partition coefficient (log Pow)

log Pow 2.54

# 10. Stability and reactivity

#### 10.4. Conditions to avoid

If product is heated above decomposition temperature toxic vapours may be released.

### 10.5. Incompatible materials

Strong oxidising agents, strong acids

### 10.6. Hazardous decomposition products

Hazardous determin decomposition products: Carbon monoxide and carbon dioxide, Chlorine compounds

# 11. Toxicological information

## 11.1. Information on toxicological effects



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Acute oral toxicity

Species rat

LD50 215 mg/kg

Species mouse

LD50 500 mg/kg

Skin corrosion/irritation

Remarks No data available.

Serious eye damage/irritation

Remarks No data available.

Sensitization

Remarks No data available.

Mutagenicity

valuation No mutagenicity in the Ames-test.

Carcinogenicity

valuation No negative effects

**Experience in practice** 

disorders of the central nervous system. Possible risk of harm to the unborn child. May cause harm to

breastfed babies.

Other information

Women of childbearing age should avoid the contact with the product.

# 12. Ecological information

## 12.1. Toxicity

# Fish toxicity

Species zebra fish (Brachydanio rerio)

LC50 4.3 mg/l Duration of exposure 96 h

**Daphnia toxicity** 

Species Daphnia magna

EC50 7.1 mg/l

Duration of exposure 48 h

Algae toxicity

EbC50 11.4 mg/l

Duration of exposure 72 h

**Bacteria toxicity** 

EC/LC50 > 100 mg/l

## 12.2. Persistence and degradability

**Biodegradability** 

Value 6 %

Duration of test 28 d valuation not degradable

## 12.3. Bioaccumulative potential

## Octanol/water partition coefficient (log Pow)

log Pow 2.54

## 12.5. Results of PBT and vPvB assessment



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#### Evaluation of persistance and bioaccumulation potential

Due to the distribution coefficient n-octanol/water, accumulation in organisms is not to be expected.

#### 12.6. Other adverse effects

#### General information / ecology

Do not allow it to reach ground water, water bodies or sewage system.

# 13. Disposal considerations

#### 13.1. Waste treatment methods

## Disposal recommendations for the product

EWC waste code Should not be released into the sanitary sewer system.

Disposal in compliance with local and national regulations.

#### Disposal recommendations for packaging

Dispose of as unused product.

# 14. Transport information

## Land transport ADR/RID

14.1. **UN** number

**UN 2811** 

14.2. UN proper shipping name

TOXIC SOLID, ORGANIC, N.O.S

14.3. Transport hazard class(es)

Class 6.1 Label 6.1

14.4. Packing group

Packing group III

#### Marine transport IMDG/GGVSee

14.1. UN number

UN 2811

14.2. UN proper shipping name

TOXIC SOLID, ORGANIC, N.O.S

14.3. Transport hazard class(es)

Class 6.1

14.4. Packing group

Packing group III

#### Air transport ICAO/IATA

14.1. UN number

UN 2811

14.2. UN proper shipping name

TOXIC SOLID, ORGANIC, N.O.S

14.3. Transport hazard class(es)

Class 6.1

14.4. Packing group

Packing group III

# 15. Regulatory information

# 16. Other information

R-phrases listed in chapter 3

22 Harmful if swallowed.



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# Hazard statements listed in chapter 3

H302 Harmful if swallowed.

## **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.