

1 Identification

- **Product identifier**
- **Trade name: Midazolam hydrochloride
Midazolami HCl**
- **Article number:** 100745
- **CAS Number:**
59467-96-8
- **EC number:**
261-776-6
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Services B.V.
Molenwerk 13, UITGEEST, 1911DB
Netherlands
Phone: +31251361400

- Supplier
Azelis Australia
Suite 217
117 Old Pittwater Road
Brookvale
NSW 2100
Australia
Phone: +61 0299392188
Fax: +61 0299392799
e-mail: info@azelis.com.au
- **Further information obtainable from:** info@fagron.com.au
- **Emergency telephone number:**
In case of emergency, please call your local poisons:
Emergency Australia: 13 11 26
Emergency NZ: 0800 764 766 (0800 POISON)

- 1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE:
+44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65
3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333
(English only)

2 Hazard(s) Identification

- **Classification of the substance or mixture**

Acute Tox. 4	H302	Harmful if swallowed.
Repr. 2	H361d-H362	Suspected of damaging the unborn child. May cause harm to breast-fed children.
STOT SE 3	H336	May cause drowsiness or dizziness.

- **Label elements**

- **GHS label elements**

The substance is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard statements**

Harmful if swallowed.

Suspected of damaging the unborn child. May cause harm to breast-fed children.

May cause drowsiness or dizziness.

· **Precautionary statements**

Do not breathe dusts or mists.

Avoid contact during pregnancy/while nursing.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Substances**

· **CAS No. Description**

CAS: 59467-96-8 Midazolam hydrochloride

Midazolami HCl

· **Identification number(s)**

· **EC number:** 261-776-6

4 First Aid Measures

· **General information:**

Immediately remove any clothing soiled by the product.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:**

In case of unconsciousness place patient stably in side position for transportation.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:** Do not induce vomiting; call for medical help immediately.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed**

Dizziness

Nausea

Gastric or intestinal disorders

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
Carbon dioxide
Water spray
Fire-extinguishing powder
Foam
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
In case of fire, the following can be released:
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Hydrogen fluoride (HF)
Hydrogen chloride (HCl)
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Avoid formation of dust.
- **Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
Thorough dedusting.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.

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- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

Rubber gloves

PVC or PE gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:** Crystalline powder

- **Colour:** Whitish

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

- **Melting point/freezing point:** Undetermined.

- **Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Product is not flammable.

- **Decomposition temperature:** Not determined.

- **Ignition temperature:** Not determined.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

- **Lower:** Not determined.

- **Upper:** Not determined.

- **Vapour pressure:** Not applicable.

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapour density** Not applicable.

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|--|--|
| · Evaporation rate | Not applicable. |
| · Solubility in / Miscibility with water: | Not determined. |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| · Dynamic: | Not applicable. |
| · Kinematic: | Not applicable. |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** Reacts with strong oxidising agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
Carbon monoxide and carbon dioxide
Nitrogen oxides (NO_x)
Hydrogen chloride (HCl)
Hydrogen fluoride

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

Oral	LD50	1600 mg/kg (rat)
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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
Suspected of damaging the unborn child. May cause harm to breast-fed children.
- **STOT-single exposure** May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish

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- **Additional ecological information:**
- **General notes:**
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Toxic for aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number · ADG, IMDG, IATA	not regulated
· UN proper shipping name · ADG, IMDG, IATA	not regulated
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	not regulated
· Packing group · ADG, IMDG, IATA	not regulated
· Environmental hazards:	Environmentally hazardous substance, solid
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Industrial Chemicals** Substance is not listed.
- **Standard for the Uniform Scheduling of Medicines and Poisons** Substance is not listed.
- **Australia: Priority Existing Chemicals** Substance is not listed.

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- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Product Safety Department
- **Contact:**
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

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