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

1.1. Product identifier
- Product form: Substance
- Trade name: MIDAZOLAM CRS
- EC no: 261-774-5
- CAS No: 59467-70-8
- Product code: M2200000
- Other means of identification: RTECS No: NI2922190

1.2. Relevant identified uses of the substance or mixture and uses advised against
1.2.1. Relevant identified uses
- Main use category: The product is intended for research, analysis and scientific education.
- Use of the substance/mixture: For professional use only
- Function or use category: Laboratory chemicals

1.2.2. Uses advised against
- No additional information available

1.3. Details of the supplier of the safety data sheet
- European Directorate for the Quality of Medicines & Healthcare
- EDOM, Council of Europe
- F-67081 Strasbourg
- T +33(0)388412035 - F +33(0)388412771

1.4. Emergency telephone number
- Emergency number: +44(0)1235239670

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
- Acute Tox. 3 (Oral): H301
- Resp. Sens. 1: H334
- Acute Tox. 4 (Dermal): H312
- Acute Tox. 4 (Inhalation): H332
- Repr. 2: H361d
- Lact: H362
- Skin Sens. 1: H317
- Aquatic Chronic 2: H411

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC
- Repr.Cat.3; R63
- Xn; R20/21/22
- Xn; R42
- Xi; R43
- N; R51/53
- R64
Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects
- No additional information available
2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP):

- GHS06
- GHS08
- GHS09

Signal word (CLP): Danger

Hazard statements (CLP):
- H301 - Toxic if swallowed
- H312 - Harmful in contact with skin
- H317 - May cause an allergic skin reaction
- H332 - Harmful if inhaled
- H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H361d - Suspected of damaging the unborn child
- H362 - May cause harm to breast-fed children
- H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP):
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P260 - Do not breathe dust/fume/gas/mist/vapours/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash hands and other exposed areas thoroughly after handling
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P273 - Avoid release to the environment
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P285 - In case of inadequate ventilation wear respiratory protection
- P301+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water
- P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
- P304+P341 - IF INHALED: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
- P308+P313 - IF exposed or concerned: Get medical advice/attention
- P312 - Call a POISON CENTER/doctor/physician if you feel unwell
- P330 - Rinse mouth
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
- P391 - Collect spillage
- P501 - Dispose of contents/container to: Hazardous waste. Comply with applicable regulations

2.3. Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Directive 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIDAZOLAM (Main constituent)</td>
<td>(CAS No)59467-70-8 (EC no)261-774-5</td>
<td>≤ 100</td>
<td>Repr.Cat.3; R63 Xn; R20/21/22 Xn; R42 Xi; R43 N; R51/53 R64</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIDAZOLAM (Main constituent)</td>
<td>(CAS No)59467-70-8 (EC no)261-774-5</td>
<td>≤ 100</td>
<td>Acute Tox. 3 [Oral], H301 Resp. Sens. 1, H334 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (inhalation), H332 Repr. 2, H361d Lact, H362 Skin Sens. 1, H317 Aquatic Chronic 2, H411</td>
</tr>
</tbody>
</table>

Full text of R-, H- and EUH-phrases: see section 16

3.2. Mixture

Not applicable
### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<table>
<thead>
<tr>
<th>Part</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-aid measures general</td>
<td>If you feel unwell, seek medical advice (show the label where possible). Delayed adverse effects possible. Active component. Pharmaceuticals. For further information refer to Summary of Product Characteristics.</td>
</tr>
<tr>
<td>First-aid measures after inhalation</td>
<td>Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.</td>
</tr>
<tr>
<td>First-aid measures after skin contact</td>
<td>Rinse skin with water/shower. Wash with plenty of soap and water.</td>
</tr>
<tr>
<td>First-aid measures after eye contact</td>
<td>Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.</td>
</tr>
<tr>
<td>First-aid measures after ingestion</td>
<td>Rinse mouth out with water. The following symptoms may occur: (see section(s) : 2, 4.2). If you feel unwell, seek medical advice. Prolonged medical observation may be indicated. (see section(s) : 4.3). The affected person must rest and be kept under medical observation.</td>
</tr>
</tbody>
</table>

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


#### 4.3. Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention. If possible show this sheet, if not available show packaging or label. If the occupational exposure limit is exceeded: Specific medical surveillance.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

| Suitable extinguishing media | Small amounts: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Large amounts: Not applicable. |
| Unsuitable extinguishing media | Water may be ineffective in firefighting due to low solubility. |

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

No additional information available

#### 5.3. Advice for firefighters

Precautionary measures fire: Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.

### SECTION 6: Accidental release measures

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

| General measures | Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Large amounts: Not applicable. |

##### 6.1.1. For non-emergency personnel

Protection equipment: See Headings 7 and 8.

Emergency procedures: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Wear suitable protective clothing and gloves.

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

No additional information available

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

Methods for cleaning up: Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents. Collect all waste in suitable and labelled containers and dispose according to local legislation. Wash the non-recoverable remainder with: Sodium hypochlorite solution.

#### 6.4. Reference to other sections

(see section(s) : 8, 13).
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed: Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended. Avoid contact during pregnancy/while nursing.

Precautions for safe handling: Handle and open container with care. See Heading 8. Do not handle until all safety precautions have been read and understood. Avoid any direct contact with the product. Obtain special instructions before use.

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures. Small amounts: Material should be handled in a laboratory hood whenever possible.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures: Comply with applicable regulations.

Storage conditions: To guarantee the quality and properties of the product, keep: dry. Keep in a cool, well-ventilated place away from heat. Store in original container. Store according to local legislation.

Incompatible products: Strong oxidizing agents.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls: Material should be handled in a laboratory hood whenever possible.


Hand protection: Gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent).

Eye protection: Wear eye protection. DIN EN 166.

Skin and body protection: Lab coat. Wear suitable protective clothing. DIN EN 13034.

Respiratory protection: Quarter mask (DIN EN 140). Wear appropriate breathing apparatus if air renewal not sufficient to maintain dust/vapour under TLV.
**SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Crystalline powder. white. light yellow. Powder.</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>Not applicable. See Heading 2, 4.2, 8.</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>295 - 298 °C</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Self ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Acetone. Propylene glycol. Water: &lt; 1 mg/l</td>
</tr>
<tr>
<td>Log Pow</td>
<td>2.54 at 20°C</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2. Other information

No additional information available

**SECTION 10: Stability and reactivity**

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

**SECTION 11: Toxicological information**

11.1. Information on toxicological effects

Acute toxicity: Toxic if swallowed. Harmful in contact with skin. Harmful if inhaled.

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MIDAZOLAM CRS</strong></td>
<td></td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>215 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>100,000 mg/kg</td>
</tr>
<tr>
<td>ATE (dermal)</td>
<td>1100,000 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

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MIDAZOLAM CRS
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<table>
<thead>
<tr>
<th>Respiratory or skin sensitisation</th>
<th>May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Suspected of damaging the unborn child. May cause harm to breast-fed children.</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
</tr>
<tr>
<td>Potential Adverse human health effects and symptoms</td>
<td>Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. See first aid section of this material safety data sheet. Large amounts: Not applicable.</td>
</tr>
</tbody>
</table>

SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>MIDAZOLAM CRS(59467-70-8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes 1</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability
MIDAZOLAM CRS(59467-70-8)
Biodegradation: 6

12.3. Bioaccumulative potential
MIDAZOLAM CRS(59467-70-8)
Log Pow: 2.54 at 20°C

12.4. Mobility in soil
No additional information available

12.5. Results of PBT and vPvB assessment
No additional information available

12.6. Other adverse effects
No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Regional legislation (waste): Dispose in a safe manner in accordance with local/national regulations.
Waste disposal recommendations: Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information
In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

14.1. UN number
UN-No: 2811
UN-No.(IATA): 2811
UN-No. (IMDG): 2811

14.2. UN proper shipping name
Proper Shipping Name: TOXIC SOLID, ORGANIC, N.O.S.
Transport document description: UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E)

14.3. Transport hazard class(es)
Class (UN): 6.1
Class (IATA): 6.1
Class (IMDG): 6.1

14.4. Packing group
Packing group (UN): III
Packing group (IMDG): III
## 14.5. Environmental hazards

Dangerous for the environment

Other information: No supplementary information available.

## 14.6. Special precautions for user

### 14.6.1. Overland transport

- **Hazard identification number (Kemler No.):** 60
- **Classification code (UN):** T2
- **Orange plates:**

  ![Orange plates](image)

  - Tunnel restriction code: E
  - LO: LO09
  - Excepted quantities (ADR): E1

### 14.6.2. Transport by sea

- **Ship Safety Act:** Toxic and infectious substances/Toxic substances
- **Port Regulation Law:** Toxic and infectious substances/Toxic substances
- MFAG-No: 154

### 14.6.3. Air transport

- **Civil Aeronautics Law:** Toxic and infectious substances/Toxic substances

## 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information
Full text of R-, H- and EUH-phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 3 (Oral)</th>
<th>Acute toxicity (oral), Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4 (Dermal)</td>
<td>Acute toxicity (dermal), Category 4</td>
</tr>
<tr>
<td>Acute Tox. 4 (Inhalation)</td>
<td>Acute toxicity (inhal.), Category 4</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 2</td>
</tr>
<tr>
<td>Lact</td>
<td>Reproductive toxicity, Additional category, Effects on or via lactation</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity, Category 2</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Sensitisation — Respiratory, category 1</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Sensitisation — Skin, category 1</td>
</tr>
<tr>
<td>H301</td>
<td>Toxic if swallowed</td>
</tr>
<tr>
<td>H312</td>
<td>Harmful in contact with skin</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H332</td>
<td>Harmful if inhaled</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
<tr>
<td>H361d</td>
<td>Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H362</td>
<td>May cause harm to breast-fed children</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>R20/21/22</td>
<td>Harmful by inhalation, in contact with skin and if swallowed</td>
</tr>
<tr>
<td>R42</td>
<td>May cause sensitization by inhalation</td>
</tr>
<tr>
<td>R43</td>
<td>May cause sensitisation by skin contact</td>
</tr>
<tr>
<td>R51/53</td>
<td>Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment</td>
</tr>
<tr>
<td>R63</td>
<td>Possible risk of harm to the unborn child</td>
</tr>
<tr>
<td>R64</td>
<td>May cause harm to breastfed babies</td>
</tr>
<tr>
<td>N</td>
<td>Dangerous for the environment</td>
</tr>
<tr>
<td>Xi</td>
<td>Irritant</td>
</tr>
<tr>
<td>Xn</td>
<td>Harmful</td>
</tr>
</tbody>
</table>

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.