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

1.1. Product identifier
Product form: Substance
Trade name: MIRTAZAPINE CRS
EC no : 288-060-6
CAS No : 85650-52-8
Product code: Y0000705
Other means of identification: RTECS No : UQ4410250

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
EDQM, 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. 4 (Dermal) H312
Acute Tox. 4 (Inhalation) H332
Acute Tox. 4 (Oral) H302
Aquatic Chronic 2 H411

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC
Xn; R20/21/22
N; R51/53
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)

- ![](image1)
- ![](image2)

**Signal word (CLP)**: Warning

**Hazard statements (CLP)**:
- H302 - Harmful if swallowed
- H312 - Harmful in contact with skin
- H332 - Harmful if inhaled
- H411 - Toxic to aquatic life with long lasting effects

**Precautionary statements (CLP)**:
- P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
- P264 - Wash hands and other exposed areas thoroughly after handling
- P273 - Avoid release to the environment
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
- 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
- P312 - Call a POISON CENTER/doctor/physician if you feel unwell
- P330 - Rinse mouth
- 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>MIRTAZAPINE (Main constituent)</td>
<td>*(CAS No)*85650-52-8 *(EC no)*288-060-6</td>
<td>≤ 100</td>
<td>Xn; R20/21/22 N; R51/53</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>MIRTAZAPINE (Main constituent)</td>
<td>*(CAS No)*85650-52-8 *(EC no)*288-060-6</td>
<td>100</td>
<td>Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302 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

- **First-aid measures after inhalation**: Move to fresh air in case of accidental inhalation. Assure fresh air breathing.
- **First-aid measures after skin contact**: Rinse skin with water/shower.
- **First-aid measures after eye contact**: Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **First-aid measures after ingestion**: Rinse mouth out with water.

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

**Symptoms/injuries**: See Heading 2.

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

In all cases of doubt, or when symptoms persist, seek medical attention.
SECTION 5: Firefighting measures

5.1. Extinguishing media

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. Large amounts: Not applicable.

6.1.1. For non-emergency personnel
Protective equipment: See Headings 7 and 8.

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.

6.4. Reference to other sections
No additional information available

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.

Precautions for safe handling: Handle and open container with care. See Heading 8.

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures.

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.

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
Hand protection: Gloves.

Skin and body protection: Lab coat.

Respiratory protection: Quarter mask (DIN EN 140).
### 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>white. Powder.</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7 (0.03%)</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</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>Ethanol. Methylene chloride. Water: &lt; 1 mg/l</td>
</tr>
<tr>
<td>Log Pow</td>
<td>3.09 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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Harmful in contact with skin. Harmful if inhaled. Harmful if swallowed.</td>
</tr>
</tbody>
</table>

**MIRTAZAPINE CRS(85650-52-8)**

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>320 - 490 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>500,000 mg/kg</td>
</tr>
<tr>
<td>ATE (dermal)</td>
<td>1100,000 mg/kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skin corrosion/irritation</th>
<th>Not classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7 (0.03%)</td>
</tr>
</tbody>
</table>
Serious eye damage/irritation: Not classified  
P<sub>H</sub>: 7 (0.03%)

Respiratory or skin sensitisation: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Specific target organ toxicity (repeated exposure): Not classified

Aspiration hazard: Not classified

Potential Adverse human health effects and symptoms: 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. Large amounts: Not applicable.

SECTION 12: Ecological information

12.1. Toxicity


### MIRTAZAPINE CRS(85650-52-8)

| LC50 fishes 1 | 6.96 mg/l | LC50 96 Hour - fish |
| EC50 Daphnia 1 | 19.9 mg/l | EC50 - 48 Hour - Daphnia magna |

12.2. Persistence and degradability

### MIRTAZAPINE CRS(85650-52-8)

| Biodegradation | 0 |

12.3. Bioaccumulative potential

### MIRTAZAPINE CRS(85650-52-8)

| Log Pow | 3.09 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 | 3077 |
| UN-No.(IATA) | 3077 |
| UN-No. (IMDG) | 3077 |

14.2. UN proper shipping name

### Proper Shipping Name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

### Transport document description

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (E)

14.3. Transport hazard class(es)

| Class (UN) | 9 |
| Class (IATA) | 9 |
| Class (IMDG) | 9 |

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.) : 90
Classification code (UN) : M7
Orange plates : 3077

Tunnel restriction code : E
LO : LO27
Excepted quantities (ADR) : E1

14.6.2. Transport by sea

Ship Safety Act : Miscellaneous dangerous substances & articles
MFAG-No : 171

14.6.3. Air transport

Civil Aeronautics Law : Miscellaneous dangerous substances & articles

14.6.4. 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. 4 (Dermal)</th>
<th>Acute toxicity (dermal), Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4 (Inhalation)</td>
<td>Acute toxicity (inhal.), Category 4</td>
</tr>
<tr>
<td>Acute Tox. 4 (Oral)</td>
<td>Acute toxicity (oral), Category 4</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 2</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H312</td>
<td>Harmful in contact with skin</td>
</tr>
<tr>
<td>H332</td>
<td>Harmful if inhaled</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>R51/53</td>
<td>Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment</td>
</tr>
<tr>
<td>N</td>
<td>Dangerous for the environment</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