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

#### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product form</th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance name</td>
<td>Detomidine</td>
</tr>
<tr>
<td>Product code</td>
<td>201600265</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Detomidine, salts, hydrates, isomers and impurities where applicable</td>
</tr>
<tr>
<td>Other means of identification</td>
<td>Ph.Eur. 1414</td>
</tr>
</tbody>
</table>

#### 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

- **Restrictions on use**: Do not use: Ingestion, Inhalation, Dermal

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

European Directorate for the Quality of Medicines & Healthcare EDQM, Council of Europe 67081 Strasbourg - France T +33(0)388412035 - F +33(0)388412771 sdss@edqm.eu - www.edqm.eu

#### 1.4. Emergency telephone number

**Emergency number**: +33(0)390215608

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

- **Classification according to Regulation (EC) No. 1272/2008 [CLP]**
  - Acute toxicity (oral), Category 3 H301
  - Acute toxicity (inhal.), Category 3 H331
  - Specific target organ toxicity — Single exposure, Category 3, Narcosis H336

Full text of H statements: see section 16

**Adverse physicochemical, human health and environmental effects**

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

- **Labelling according to Regulation (EC) No. 1272/2008 [CLP]**
  - **Hazard pictograms (CLP)**: GHS06
  - **Signal word (CLP)**: Danger
  - **Hazard statements (CLP)**: H301+H331 - Toxic if swallowed or if inhaled
  - **Precautionary statements (CLP)**: P301+P310 - IF SWALLOWED: Immediately call a doctor
  - **P261 - Avoid breathing dust, vapours**
  - **P304 - IF INHALED:**
  - **P311 - Call a doctor**
Detomidine
Safety Data Sheet

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP):

GHS06

2.3. Other hazards
No additional information available

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 Regulation (EC No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detomidine</td>
<td>&lt;= 100</td>
<td></td>
<td>Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 STOT SE 3, H336</td>
</tr>
</tbody>
</table>

Full text of H-statements: see section 16

3.2. Mixtures
Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: Move to fresh air. Assure fresh air breathing.
First-aid measures after skin contact: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of soap and water.
First-aid measures after eye contact: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion: Rinse mouth. Immediately call a POISON CENTER or doctor/physician. Specific medical surveillance.

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

Symptoms/effects: Cardiac disorders.
Symptoms/effects after inhalation: Insufficient data available.
Symptoms/effects after skin contact: Insufficient data available.
Symptoms/effects after eye contact: Insufficient data available.
Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media: Extinguishing blanket.

5.2. Special hazards arising from the substance or mixture
Fire hazard: See Heading 2.2.

5.3. Advice for firefighters
Firefighting instructions: Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.1. For non-emergency personnel
No additional information available

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: Ensure waste is collected and contained. Clean thoroughly.

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: 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.
Precautions for safe handling: Material should be handled with caution. Avoid any direct contact with the product.
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: Store locked up.

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:
Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

Hand protection:
Chemically resistant protective gloves. EN 374

Eye protection:
Safety glasses. DIN EN 166

Skin and body protection:
Use chemically protective clothing. DIN EN 13034

Respiratory protection:
Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

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>Powder.</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>Not applicable.</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>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>Auto-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>
</tbody>
</table>
Detomidine
Safety Data Sheet

Relative vapour density at 20 °C : No data available
Relative density : No data available
Solubility : Water: 33.3 - 100 g/l
Log Pow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

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
No additional information available

10.4. Conditions to avoid
No additional information available

10.5. Incompatible materials
None under normal use. See Heading 7.

10.6. Hazardous decomposition products
When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity : Oral: Toxic if swallowed. Inhalation: Toxic if inhaled.

<table>
<thead>
<tr>
<th>Detomidine</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>50 - 300 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/iritation : Not classified (Lack of data)
Serious eye damage/iritation : Not classified (Lack of data)
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Lack of data)
Carcinogenicity : Not classified (Lack of data)
Reproductive toxicity : Not classified (Further details: Acute toxicity)
STOT-single exposure : May cause drowsiness or dizziness.
STOT-repeated exposure : Not classified (Further details: STOT-single exposure)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity
Ecology - general : Hazardous waste. Use suitable disposal containers.

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
No additional information available

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.

Product/Packaging 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 / IATA / IMDG

<table>
<thead>
<tr>
<th>ADR</th>
<th>UN number</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1.</td>
<td>UN number</td>
<td>2811</td>
<td>2811</td>
</tr>
</tbody>
</table>

| 14.2. | UN proper shipping name | TOXIC SOLID, ORGANIC, N.O.S. | TOXIC SOLID, ORGANIC, N.O.S. | Toxic solid, organic, n.o.s. |

Transport document description

| UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E) | UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III | UN 2811 Toxic solid, organic, n.o.s., 6.1, III |

14.3. Transport hazard class(es)

| 6.1 |

| 6 |

14.4. Packing group

| III |

| III |

14.5. Environmental hazards

| Dangerous for the environment : No |

| Dangerous for the environment : No |

| Marine pollutant : No |

| No supplementary information available |

14.6. Special precautions for user

- Overland transport

| Classification code (ADR) | T2 |

| Special provisions (ADR) | 274, 614 |

| Limited quantities (ADR) | 5kg |

| Excepted quantities (ADR) | E1 |

| Packing instructions (ADR) | P002, IBC08, LP02, R001 |

| Special packing provisions (ADR) | B3 |

| Mixed packing provisions (ADR) | MP10 |

| Portable tank and bulk container instructions (ADR) | T1 |

| Portable tank and bulk container special provisions (ADR) | TP33 |

| Tank code (ADR) | SGAH, L4BH |

| Tank special provisions (ADR) | TU15, TE19 |

| Vehicle for tank carriage | AT |

| Transport category (ADR) | 2 |

| Special provisions for carriage - Bulk (ADR) | VC1, VC2, AP7 |

| Special provisions for carriage - Loading, unloading and handling (ADR) | CV13, CV28 |

| Special provisions for carriage - Operation (ADR) | S9 |

| Hazard identification number (Kemler No.) | 60 |

| Orange plates | 2811 |
Detomidine
Safety Data Sheet

Tunnel restriction code (ADR) : E

- Transport by sea
Special provisions (IMDG) : 223, 274
Limited quantities (IMDG) : 5 kg
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P002
IBC packing instructions (IMDG) : IBC08
IBC special provisions (IMDG) : B3
Tank instructions (IMDG) : T1
Tank special provisions (IMDG) : TP33
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-A
Stowage category (IMDG) : A
Properties and observations (IMDG) : Toxic if swallowed, by skin contact or by inhalation.

- Air transport
PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y645
PCA limited quantity max net quantity (IATA) : 10kg
PCA packing instructions (IATA) : 670
PCA max net quantity (IATA) : 100kg
CAO packing instructions (IATA) : 677
CAO max net quantity (IATA) : 200kg
Special provisions (IATA) : A3, A5
ERG code (IATA) : 6L

14.7. Transport in bulk according to Annex II of Marpol 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
Detomidine is not on the REACH Candidate List
Detomidine is not on the REACH Annex XIV List

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 H- and EUH-statements:

<table>
<thead>
<tr>
<th>Acute Tox. 3 (Inhalation)</th>
<th>Acute toxicity (inhal.), Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 3 (Oral)</td>
<td>Acute toxicity (oral), Category 3</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity — Single exposure, Category 3, Narcosis</td>
</tr>
<tr>
<td>H301</td>
<td>Toxic if swallowed</td>
</tr>
<tr>
<td>H331</td>
<td>Toxic if inhaled</td>
</tr>
<tr>
<td>H336</td>
<td>May cause drowsiness or dizziness</td>
</tr>
</tbody>
</table>

SDS EU (REACH Annex II)

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