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

1.1. Product identifier

| Product form | Substance |
| Trade name | PAROXETINE HYDROCHLORIDE HEMIHYDRATE CRS |
| CAS No | 110429-35-1 |
| Product code | Y0000281 |
| Other means of identification | RTECS No : TM4569320 (paroxetine hydrochloride anhydrous) |

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]

| Eye Dam. 1 | H318 |
| Acute Tox. 4 (Oral) | H302 |
| Repr. 2 | H361d |
| STOT SE 3 | H335 |
| 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; R22 |
| Xi; R41 |
| Xi; R37 |
| 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):

<table>
<thead>
<tr>
<th>GHS05</th>
<th>GHS09</th>
<th>GHS07</th>
<th>GHS08</th>
</tr>
</thead>
</table>

Signal word (CLP): Danger

Hazard statements (CLP):
- H302 - Harmful if swallowed
- H318 - Causes serious eye damage
- H335 - May cause respiratory irritation
- H361d - Suspected of damaging the unborn child
- 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
- 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
- P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
- P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P308+P313 - IF exposed or concerned: Get medical advice/attention
- P310 - Immediately call a POISON CENTER or doctor/physician
- P312 - Call a POISON CENTER/doctor/physician if you feel unwell
- P330 - Rinse mouth
- P391 - Collect spillage
- P403+P233 - Store in a well-ventilated place. Keep container tightly closed
- 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>PAROXETINE HYDROCHLORIDE HEMIHYDRATE (Main constituent)</td>
<td>(CAS No)110429-35-1</td>
<td>≤ 100</td>
<td>Repr.Cat.3; R63 Xn; R22 Xi; R41 Xi; R37 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>PAROXETINE HYDROCHLORIDE HEMIHYDRATE (Main constituent)</td>
<td>(CAS No)110429-35-1</td>
<td>≤ 100</td>
<td>Eye Dam. 1, H318 Acute Tox. 4 (Oral), H302 Repr. 2, H361d STOT SE 3, H335 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 general
If you feel unwell, seek medical advice (show the label where possible). Delayed adverse effects possible. Immediately flush the contact area with plenty of water. Active component. Pharmaceuticals. For further information refer to Summary of Product Characteristics.

First-aid measures after inhalation
Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists. If breathing is difficult, give oxygen.

First-aid measures after skin contact
Rinse skin with water/shower. Wash with plenty of soap and water. Flush with lukewarm water for 15 minutes. If skin irritation persists, take medical advice.

First-aid measures after eye contact
Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist. Continue to rinse eye with clean water for 20-30 minutes, retracting eyelids often.

First-aid measures after ingestion
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). Do NOT induce vomiting. The affected person must rest and be kept under medical observation.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/injuries

Symptoms/injuries after inhalation
Respiratory, thoracic and mediastinal disorders. May cause shortness of breath, tightness of the chest, a sore throat and cough.

Symptoms/injuries after skin contact
Skin and subcutaneous tissue disorders. Skin corrosion/irritation. Redness, pain.

Symptoms/injuries after eye contact
Direct contact may result in corneal injury. Redness, pain.

Symptoms/injuries after ingestion
Gastrointestinal disorders. Burns to the gastric/intestinal mucosa.

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. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media
Small amounts: Use extinguishing media appropriate for surrounding fire. Large amounts: Not applicable.

5.2. Special hazards arising from the substance or mixture
Fire hazard
Beware, risk of formation of toxic and corrosive gases.

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. Causes burns. Avoid all contact with skin, eyes, or clothing. Do not breathe dust/fume/gas/mist/vapours/spray. Large amounts: Not applicable.

6.1.1. For non-emergency personnel
Protective 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. 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).

10/08/2013
EN (English)
### 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.

**Personal protective equipment**

**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. 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>139 - 140 °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>Methanol. Methylene chloride.</td>
</tr>
<tr>
<td>Log Pow</td>
<td>1,3 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: Harmful if swallowed.

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAROXETINE HYDROCHLORIDE HEMIHYDRATE CRS(110429-35-1)</td>
<td></td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>415 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>500,000 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Not classified

Serious eye damage/irritation: Causes serious eye damage.

Respiratory or skin sensitisation: Not classified

Germ cell mutagenicity: Not classified
PAROXETINE HYDROCHLORIDE HEMIHYDRATE CRS
Safety Data Sheet

Carcinogenicity : Not classified
Reproductive toxicity : Suspected of damaging the unborn child.
Specific target organ toxicity (single exposure) : May cause respiratory irritation.
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. See first aid section of this material safety data sheet. Large amounts: Not applicable.

SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>PAROXETINE HYDROCHLORIDE HEMIHYDRATE CRS(110429-35-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 Daphnia 1</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
No additional information available

<table>
<thead>
<tr>
<th>PAROXETINE HYDROCHLORIDE HEMIHYDRATE CRS(110429-35-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
</tr>
</tbody>
</table>

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: [Image]

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: [Image]

- Tunnel restriction code: E
- LO: LQ27
- 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

14.7. **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>R-phrase</th>
<th>EUH-phrases</th>
</tr>
</thead>
<tbody>
<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>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation, Category 1</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity, Category 2</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
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<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H361d</td>
<td>Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>R22</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>R37</td>
<td>Irritating to respiratory system</td>
</tr>
<tr>
<td>R41</td>
<td>Risk of serious damage to eyes</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>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.