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

1.1. Product identifier

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product form</td>
<td>Substance</td>
</tr>
<tr>
<td>Trade name</td>
<td>XYLOMETAZOLINE HYDROCHLORIDE CRS</td>
</tr>
<tr>
<td>EC no</td>
<td>214-936-4</td>
</tr>
<tr>
<td>CAS No</td>
<td>1218-35-5</td>
</tr>
<tr>
<td>Product code</td>
<td>X0100000</td>
</tr>
<tr>
<td>Other means of identification</td>
<td>RTECS No : NJ2390000</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

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. 3 (Oral)       H301
Eye Dam. 1                H318
Aquatic Chronic 3         H412

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xn; R22
Xi; R41
R52/53

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available
XYLOMETAZOLINE HYDROCHLORIDE CRS
Safety Data Sheet

2.2. Label elements

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

Hazard pictograms (CLP):

GHS06
GHS05

Signal word (CLP): Danger

Hazard statements (CLP):
H301 - Toxic if swallowed
H318 - Causes serious eye damage
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP):
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+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P330 - Rinse mouth
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>
</table>
| XYLOMETAZOLINE HYDROCHLORIDE (Main constituent) | (CAS No) 1218-35-5  
(CEN no)214-936-4               | ≤ 100 | Xn; R22  
Xi; R41  
R52/53                               |

<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>
</table>
| XYLOMETAZOLINE HYDROCHLORIDE (Main constituent) | (CAS No) 1218-35-5  
(CEN no)214-936-4               | ≤ 100 | Acute Tox. 3 (Oral), H301  
Eye Dam. 1, H318  
Aquatic Chronic 3, H412            |

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). Immediately flush the contact area with plenty of water.

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. Do NOT induce vomiting.
4.2. Most important symptoms and effects, both acute and delayed
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. Treat symptomatically.

SECTION 5: Firefighting measures
5.1. Extinguishing media

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.
Firefighting instructions: Dilute with water.

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. 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. Clean with water. Collect all waste in suitable and labelled containers and dispose according to local legislation.

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.
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.
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.
XYLOMETAZOLINE HYDROCHLORIDE CRS
Safety Data Sheet

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

Physical state: Solid
Appearance: Crystalline powder. white. Powder.
Colour: No data available
Odour: Not applicable. See Heading 2, 4.2, 8.
Odour threshold: No data available
pH: No data available
Relative evaporation rate (butylacetate=1): No data available
Melting point: 317 - 329 °C
Freezing point: No data available
Boiling point: No data available
Flash point: > 100 °C
Self ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): No data available
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: No data available
Solubility: Ethanol. Water: > 100 mg/l
Log Pow: 0,36 at 20°C
Log Kow: 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
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>Acute toxicity</th>
<th>Toxic if swallowed.</th>
</tr>
</thead>
</table>

**XYLOMETAZOLINE HYDROCHLORIDE CRS(1218-35-5)**

| LD50 oral rat | 230 mg/kg |
| ATE (oral)    | 100,000 mg/kg |

- Skin corrosion/irritation: Not classified
- Serious eye damage/irritation: Causes serious eye damage.
- 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. See first aid section of this material safety data sheet. Large amounts: Not applicable.

SECTION 12: Ecological information

12.1. Toxicity


Ecology - water: Soluble in water.

**XYLOMETAZOLINE HYDROCHLORIDE CRS(1218-35-5)**

| LC50 fishes 1 | 60.61 mg/l LC50-96 Hour - fish |

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential

**XYLOMETAZOLINE HYDROCHLORIDE CRS(1218-35-5)**

| Log Pow | 0.36 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

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN-No</td>
<td>2811</td>
</tr>
<tr>
<td>UN-No.(IATA)</td>
<td>2811</td>
</tr>
<tr>
<td>UN-No. (IMDG)</td>
<td>2811</td>
</tr>
</tbody>
</table>

### 14.2. UN proper shipping name

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name</td>
<td>TOXIC SOLID, ORGANIC, N.O.S.</td>
</tr>
<tr>
<td>Transport document description</td>
<td>UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E)</td>
</tr>
</tbody>
</table>

### 14.3. Transport hazard class(es)

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class (UN)</td>
<td>6.1</td>
</tr>
<tr>
<td>Class (IATA)</td>
<td>6.1</td>
</tr>
<tr>
<td>Class (IMDG)</td>
<td>6.1</td>
</tr>
</tbody>
</table>

### 14.4. Packing group

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group (UN)</td>
<td>III</td>
</tr>
<tr>
<td>Packing group (IMDG)</td>
<td>III</td>
</tr>
</tbody>
</table>

### 14.5. Environmental hazards

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other information</td>
<td>No supplementary information available.</td>
</tr>
</tbody>
</table>

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard identification number (Kemler No.)</td>
<td>60</td>
</tr>
<tr>
<td>Classification code (UN)</td>
<td>T2</td>
</tr>
<tr>
<td>Orange plates</td>
<td>60-2811</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
<td>E</td>
</tr>
<tr>
<td>LQ</td>
<td>LQ09</td>
</tr>
<tr>
<td>Excepted quantities (ADR)</td>
<td>E1</td>
</tr>
</tbody>
</table>

#### 14.6.2. Transport by sea

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ship Safety Act</td>
<td>Toxic and infectious substances/Toxic substances</td>
</tr>
<tr>
<td>Port Regulation Law</td>
<td>Toxic and infectious substances/Toxic substances</td>
</tr>
<tr>
<td>MFAG-No</td>
<td>154</td>
</tr>
</tbody>
</table>

#### 14.6.3. Air transport

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil Aeronautics Law</td>
<td>Toxic and infectious substances/Toxic substances</td>
</tr>
</tbody>
</table>

### 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>Aquatic Chronic 3</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 3</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation, Category 1</td>
</tr>
<tr>
<td>H301</td>
<td>Toxic if swallowed</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>R22</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>R41</td>
<td>Risk of serious damage to eyes</td>
</tr>
<tr>
<td>R52/53</td>
<td>Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic 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.