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

1.1. Product identifier
Product form: Substance
Trade name: Naloxone impurity D CRS
Product code: Y0001571

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 (Oral) H302
Acute Tox. 4 (Inhalation) H332
Resp. Sens. 1 H334
Skin Sens. 1 H317
STOT SE 2 H371

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC
Not classified

Adverse physicochemical, human health and environmental effects
Impurities with unknown properties. No information available on this specific product, however by analogy, the product is considered to be: See Heading 2.2.
Naloxone impurity D CRS
Safety Data Sheet

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

Signal word (CLP) : Danger
Hazard pictograms (CLP) : GHS07 GHS08

Hazard statements (CLP) :
H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H332 - Harmful if inhaled
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H371 - May cause damage to organs

Precautionary statements (CLP) :
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P264 - Wash hands and other exposed areas thoroughly after handling
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory 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
P304+P341 - IF INHALED: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P309+P311 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician
P310 - 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
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
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>Naloxone impurity D (Main constituent)</td>
<td></td>
<td>≤ 100</td>
<td>Not classified</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>Naloxone impurity D (Main constituent)</td>
<td></td>
<td>≤ 100</td>
<td>Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Skin Sens. 1, H317 STOT SE 2, H371</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).
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.
First-aid measures after skin contact : Rinse skin with water/shower. Wash with plenty of soap and water.
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.
First-aid measures after ingestion : Rinse mouth out with water. The following symptoms may occur: (see section(s) : 2). If you feel unwell, seek medical advice.
### 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

No data available. Treat symptomatically.

### SECTION 5: Firefighting measures

**5.1. Extinguishing media**

**Suitable extinguishing media**: Small amounts: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Dry powder. Large amounts: Not applicable.

**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**: 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**: 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**: 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

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

Colour: No data available

Odour: Not applicable. See Heading 2, 4.2, 8.

Odour threshold: No data available

Relative evaporation rate (butylacetate=1): No data available

Melting point: No data available

Freezing point: No data available

Boiling point: No data available

Flash point: No data available

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: No data available

Log Pow: No data available

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

No additional information available

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: No data available.

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.
### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Harmful if swallowed. Harmful if inhaled.</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>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.</td>
</tr>
<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>Not classified</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>May cause damage to organs.</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>
</tbody>
</table>

**Potential Adverse human health effects and symptoms**

No appropriate human or animal health effects data are known to exist.

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general: Small amounts: See Heading 2. Large amounts: Not applicable.

#### 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

The statement is derived from products of similar structure or composition.

(No data available specific to the product)

### 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

No dangerous good in sense of transport regulations

#### 14.2. UN proper shipping name

Not applicable

#### 14.3. Transport hazard class(es)

Not applicable

#### 14.4. Packing group

Not applicable

#### 14.5. Environmental hazards

Other information: No supplementary information available.

#### 14.6. Special precautions for user

No additional information available
14.6.2. Transport by sea
No additional information available

14.6.3. Air transport
No additional information available

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>H-phrase</th>
<th>EUH-phrase</th>
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<tbody>
<tr>
<td>Acute Tox. 4 (Inhalation)</td>
<td>Acute toxicity (inhal.), Category 4</td>
<td></td>
</tr>
<tr>
<td>Acute Tox. 4 (Oral)</td>
<td>Acute toxicity (oral), Category 4</td>
<td></td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Sensitisation — Respiratory, category 1</td>
<td></td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Sensitisation — Skin, category 1</td>
<td></td>
</tr>
<tr>
<td>STOT SE 2</td>
<td>Specific target organ toxicity — Single exposure, Category 2</td>
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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.