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

<table>
<thead>
<tr>
<th>1.1.</th>
<th>Product identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product form</td>
<td>Mixture</td>
</tr>
<tr>
<td>Trade name</td>
<td>VALSARTAN FOR SYSTEM SUITABILITY CRS</td>
</tr>
<tr>
<td>Product code</td>
<td>Y0001145</td>
</tr>
<tr>
<td>Other means of identification</td>
<td>RTECS No : YV9455000 (Valsartan)</td>
</tr>
</tbody>
</table>

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

<table>
<thead>
<tr>
<th>1.2.1.</th>
<th>Relevant identified uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main use category</td>
<td>The product is intended for research, analysis and scientific education.</td>
</tr>
<tr>
<td>Use of the substance/mixture</td>
<td>For professional use only</td>
</tr>
<tr>
<td>Function or use category</td>
<td>Laboratory chemicals</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2.2.</th>
<th>Uses advised against</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
<td></td>
</tr>
</tbody>
</table>

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

European Directorate for the Quality of Medicines & Healthcare
EDOM, 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

<table>
<thead>
<tr>
<th>2.1.</th>
<th>Classification of the substance or mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification according to Directive 67/548/EEC or 1999/45/EC</td>
<td></td>
</tr>
<tr>
<td>Repr.Cat.3; R63</td>
<td></td>
</tr>
<tr>
<td>R52/53</td>
<td></td>
</tr>
<tr>
<td>Full text of R-phrases: see section 16</td>
<td></td>
</tr>
</tbody>
</table>

### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

<table>
<thead>
<tr>
<th>Labelling according to Directive 67/548/EEC or 1999/45/EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard symbols</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R-phrases</th>
<th>R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>R63 - Possible risk of harm to the unborn child</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S-phrases</th>
<th>S22 - Do not breathe dust</th>
</tr>
</thead>
<tbody>
<tr>
<td>S36/37 - Wear suitable protective clothing and gloves</td>
<td></td>
</tr>
<tr>
<td>S61 - Avoid release to the environment. Refer to special instructions/safety data sheets</td>
<td></td>
</tr>
</tbody>
</table>

### 2.3. Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

### SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>3.1.</th>
<th>Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

| 3.2. | Mixture |
**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
Physical state: Solid
Colour: No data available
Odour: No data available
Odour threshold: No data available
pH: 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: Water: < 1 mg/l
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
Stable under normal conditions.
### SECTION 10: Physical and Chemical Properties

#### 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**: Not classified

**VALSARTAN (137862-53-4)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Corrosivity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sensitisation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Repeated dose toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

| Toxicity for reproduction              | Possible risk of harm to the unborn child. |
| 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

**Ecology - general**: Small amounts: See Heading 2. Poorly soluble in water. No data available on ecotoxicity. Large amounts: Not applicable.

**VALSARTAN (137862-53-4)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes</td>
<td>&gt; 100 mg/l LC50-96 Hour - fish</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>&gt; 100 mg/l EC50 - 48 Hour - Daphnia magna</td>
</tr>
</tbody>
</table>

**Biodegradation**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>0</td>
</tr>
</tbody>
</table>

**VALSARTAN (137862-53-4)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>-1.1 at 20°C</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.
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

14.6.1. Overland transport
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
Contains no REACH candidate substance

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>Aquatic Chronic 3</th>
<th>Hazardous to the aquatic environment — Chronic Hazard, Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity, Category 2</td>
</tr>
<tr>
<td>H361d</td>
<td>Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</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>R63</td>
<td>Possible risk of harm to the unborn child</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.