1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form: Substance
Trade name: VALSARTAN CRS
CAS No: 137862-53-4
Product code: Y0001132
Other means of identification: RTECS No: YV9455000

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]
Repr. 2 H361d
Aquatic Chronic 3 H412

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC
Repr.Cat.3; R63
R52/53

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): GHS08

Signal word (CLP): Warning
Hazard statements (CLP): H361d - Suspected of damaging the unborn child
H412 - Harmful 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
P273 - Avoid release to the environment
P281 - Use personal protective equipment as required
P308+P313 - IF exposed or concerned: Get medical advice/attention
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>VALSARTAN (Main constituent)</td>
<td>(CAS No) 137862-53-4</td>
<td>≤ 100</td>
<td>Repr. Cat. 3; R63 R52/53</td>
</tr>
<tr>
<td>VALSARTAN (Main constituent)</td>
<td>(CAS No) 137862-53-4</td>
<td>≤ 100</td>
<td>Repr. 2, H361d Aquatic Chronic 3, H412</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 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

Appearance: white. Powder.

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: 116 - 117 °C

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: Ethanol. Methylene chloride. Water: < 1 mg/l

Log Pow: -1.1 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
Acute toxicity : Not classified

<table>
<thead>
<tr>
<th>VALSARTAN CRS(137862-53-4)</th>
<th>LD50 oral rat</th>
<th>&gt; 2000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
<td></td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>: Suspected of damaging the unborn child.</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>: Not classified</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>: Not classified</td>
<td></td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>: Not classified</td>
<td></td>
</tr>
<tr>
<td>Potential Adverse human health effects and symptoms</td>
<td>: 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.</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>VALSARTAN CRS(137862-53-4)</th>
<th>LC50 fishes 1</th>
<th>&gt; 100 mg/l LC50-96 Hour - fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 Daphnia 1</td>
<td>&gt; 100 mg/l EC50 - 48 Hour - Daphnia magna</td>
<td></td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>VALSARTAN CRS(137862-53-4)</th>
<th>Biodegradation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>VALSARTAN CRS(137862-53-4)</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td></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

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>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Chronic 3</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 3</td>
</tr>
<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 therefore be construed as guaranteeing any specific property of the product.