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

1.1. Product identifier

Product form : Substance
Trade name : BECLOMETASONE DIPROPIONATE ANHYDROUS CRS
EC no : 226-886-0
CAS No : 5534-09-8
Product code : B0305000
Other means of identification : RTECS No : TU3805000

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
Repr. 2 H361f
Aquatic Chronic 4 H413

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC
Repr.Cat.3; R62
Repr.Cat.3; R63
R53

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]

Signal word (CLP): Warning

Hazard pictograms (CLP): GHS08

Hazard statements (CLP):
- H361d - Suspected of damaging the unborn child
- H361f - Suspected of damaging fertility
- H413 - May cause long lasting harmful effects to aquatic life

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>BECLOMETASONE DIPROPIONATE ANHYDROUS (Main constituent)</td>
<td>(CAS No) 5534-09-8 (EC no) 226-886-0</td>
<td>≤ 100</td>
<td>Repr. Cat.3; R62 Repr. Cat.3; R63 R53</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>BECLOMETASONE DIPROPIONATE ANHYDROUS (Main constituent)</td>
<td>(CAS No) 5534-09-8 (EC no) 226-886-0</td>
<td>≤ 100</td>
<td>Repr. 2, H361d Repr. 2, H361f Aquatic Chronic 4, H413</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**: Crystalline powder. 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**: 117 - 120 °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**: Acetone. Water: < 1 mg/l
- **Log Pow**: 3,49 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

**BECLometasone Dipropionate Anhydrous CRS**

- **LD50 oral rat**: > 3750 mg/kg
- **Skin corrosion/irritation**: Not classified
- **Serious eye damage/irritation**: Not classified
- **Respiratory or skin sensitisation**: Not classified
- **Germ cell mutagenicity**: Not classified
**BECLOMETASONE DIPROPIONATE ANHYDROUS CRS**

Safety Data Sheet


<table>
<thead>
<tr>
<th>Carcinogenicity</th>
<th>Not classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Suspected of damaging the unborn child. Suspected of damaging fertility.</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Not classified</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>
<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>
</tr>
</tbody>
</table>

### SECTION 12: Ecological information

<table>
<thead>
<tr>
<th>12.1. Toxicity</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>12.2. Persistence and degradability</th>
</tr>
</thead>
<tbody>
<tr>
<td>BECLOMETASONE DIPROPIONATE ANHYDROUS CRS (5534-09-8)</td>
</tr>
<tr>
<td>Biodegradation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.3. Bioaccumulative potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>BECLOMETASONE DIPROPIONATE ANHYDROUS CRS (5534-09-8)</td>
</tr>
<tr>
<td>Log Pow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.4. Mobility in soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.5. Results of PBT and vPvB assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>12.6. Other adverse effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
</tr>
</tbody>
</table>

### SECTION 13: Disposal considerations

<table>
<thead>
<tr>
<th>13.1. Waste treatment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional legislation (waste)</td>
</tr>
</tbody>
</table>

### SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

<table>
<thead>
<tr>
<th>14.1. UN number</th>
</tr>
</thead>
<tbody>
<tr>
<td>No dangerous good in sense of transport regulations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.2. UN proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.3. Transport hazard class(es)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.4. Packing group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.5. Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.6. Special precautions for user</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>14.6.1. Overland transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.6.2. Transport by sea</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.6.3. Air transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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>Aquatic Chronic 4</th>
<th>Hazardous to the aquatic environment — Chronic Hazard, Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 2</td>
<td>Reproductive toxicity, Category 2</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>H361f</td>
<td>Suspected of damaging fertility</td>
</tr>
<tr>
<td>H413</td>
<td>May cause long lasting harmful effects to aquatic life</td>
</tr>
<tr>
<td>R53</td>
<td>May cause long-term adverse effects in the aquatic environment</td>
</tr>
<tr>
<td>R62</td>
<td>Possible risk of impaired fertility</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.