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

1.1. Product identifier

Product form : Substance
Substance name : Rupatadine
Product code : 201601112
Synonyms : Rupatadine, salts, hydrates, isomers and impurities where applicable

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

Restrictions on use : Do not use: Ingestion, Inhalation, Dermal

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
67081 Strasbourg - France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Acute toxicity (oral), Category 4 H302
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects
Expert judgement and weight of evidence determination.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Hazard pictograms (CLP) : GHS07

Signal word (CLP) : Warning
Hazard statements (CLP) : H302 - Harmful if swallowed
Precautionary statements (CLP) : P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml
No labelling required

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances
**Name** | **Product identifier** | **%** | **Classification according to Regulation (EC) No. 1272/2008 [CLP]**
--- | --- | --- | ---
Rupatadine | <= 100 | Acute Tox. 4 (Oral), H302

Full text of H-statements: see section 16

3.2. **Mixtures**
Not applicable

**SECTION 4: First aid measures**

4.1. **Description of first aid measures**

First-aid measures after skin contact: Wipe off as much as possible (using a clean, soft, absorbent material).
First-aid measures after eye contact: Rinse eyes with water as a precaution.

4.2. **Most important symptoms and effects, both acute and delayed**
No additional information available

4.3. **Indication of any immediate medical attention and special treatment needed**
No additional information available

**SECTION 5: Firefighting measures**

5.1. **Extinguishing media**
Suitable extinguishing media: Extinguishing blanket.

5.2. **Special hazards arising from the substance or mixture**

Fire hazard: See Heading 2.2.

5.3. **Advice for firefighters**
Firefighting instructions: Use extinguishing media appropriate for surrounding fire.

**SECTION 6: Accidental release measures**

6.1. **Personal precautions, protective equipment and emergency procedures**

6.1.1. **For non-emergency personnel**
Emergency procedures: Avoid all unnecessary exposure.

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**
No additional information available

6.4. **Reference to other sections**
No additional information available

**SECTION 7: Handling and storage**

7.1. **Precautions for safe handling**
No additional information available

7.2. **Conditions for safe storage, including any incompatibilities**
No additional information available

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:**
Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.
Hand protection:
Protective gloves

Skin and body protection:
Lab coat

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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
None known.

10.4. Conditions to avoid
No additional information available

10.5. Incompatible materials
None under normal use. See Heading 7.

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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Oral: Harmful if swallowed.</td>
</tr>
<tr>
<td>Rupatadine</td>
<td></td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>300 - 2000 mg/kg</td>
</tr>
</tbody>
</table>
Rupatadine
Safety Data Sheet

Safety Data Sheet in accordance with regulation (EC) No 1907/2006, as amended.

| **Skin corrosion/irritation**   | Not classified (Lack of data) |
| **Serious eye damage/irritation** | Not classified (Lack of data) |
| **Respiratory or skin sensitisation** | Not classified (Based on available data, the classification criteria are not met) |
| **Germ cell mutagenicity** | Not classified (Lack of data) |
| **Carcinogenicity** | Not classified (Lack of data) |
| **Reproductive toxicity** | Not classified (Further details: Acute toxicity) |
| **STOT-single exposure** | Not classified (Based on available data, the classification criteria are not met) |
| **STOT-repeated exposure** | Not classified (Further details: Acute toxicity) |
| **Aspiration hazard** | Not classified (Based on available data, the classification criteria are not met) |

**SECTION 12: Ecological information**

12.1. **Toxicity**

Ecology - general: Presents no specific risk for the environment.

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**

No additional information available

**SECTION 13: Disposal considerations**

13.1. **Waste treatment methods**

No additional information available

**SECTION 14: Transport information**

In accordance with ADR / IATA / IMDG

<table>
<thead>
<tr>
<th>ADR</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1. <strong>UN number</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.2. <strong>UN proper shipping name</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.3. <strong>Transport hazard class(es)</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.4. <strong>Packing group</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.5. <strong>Environmental hazards</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.6. <strong>Special precautions for user</strong></td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

- **Overland transport**
  Not applicable

- **Transport by sea**
  Not applicable

- **Air transport**
  Not applicable
Rupatadine
Safety Data Sheet

Safety Data Sheet in accordance with regulation (EC) No 1907/2006, as amended.

14.7. Transport in bulk according to Annex II of Marpol 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
Rupatadine is not on the REACH Candidate List
Rupatadine is not on the REACH Annex XIV List

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 H- and EUH-statements:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral), Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
</tbody>
</table>

SDS EU (REACH Annex II)

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