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

## 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>VALCYTE(R) Powder for Oral Solution (50 mg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10090308</td>
</tr>
<tr>
<td>Synonyms</td>
<td>- VALCYTE Powder for Oral Solution 50 mg/ml</td>
</tr>
<tr>
<td></td>
<td>- VALCYTE Dry Syrup 250 mg/5 ml</td>
</tr>
</tbody>
</table>

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

- pharmaceutical active substance (virostatic)  

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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phone 001-(650) 225-1000 E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a> US Chemtrec phone: (800)-424-9300</td>
</tr>
</tbody>
</table>

### 1.4. Emergency telephone number

- Emergency telephone number US Chemtrec phone: (800)-424-9300

*1 referring to: Valganciclovir hydrochloride
SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.5 Germ cell mutagenicity (Category 1A)
   H340 May cause genetic defects.

3.6 Carcinogenicity (Category 1A)
   H350 May cause cancer.

3.7 Reproductive toxicity (Category 1A)
   H360FD May damage fertility. May damage the unborn child.

3.9 Specific target organ toxicity - Repeated exposure (Category 1)
   H372 Causes damage to organs through prolonged or repeated exposure.

Signalword: Danger

Label:

Precautionary statements:

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust
- P281 Use personal protective equipment as required.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.

Other hazards

Note

- no information available

SECTION 3: Composition/information on ingredients

Characterization

consisting of 46% Valganciclovir hydrochloride, with the remainder consisting of excipients that are not classified as hazardous

Ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valganciclovir hydrochloride</td>
<td>~ 46 %</td>
</tr>
<tr>
<td></td>
<td>CAS: 175865-59-5</td>
</tr>
<tr>
<td>Fumaric acid</td>
<td>~ 2 %</td>
</tr>
<tr>
<td></td>
<td>CAS: 110-17-8</td>
</tr>
</tbody>
</table>
### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>- rinse immediately with tap water for 10 minutes - open eyelids forcibly - begin with medical treatment.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents</td>
</tr>
<tr>
<td>Inhalation</td>
<td>- remove the casualty to fresh air and keep him/her calm - get medical treatment</td>
</tr>
<tr>
<td>Ingestion</td>
<td>- summon a physician immediately</td>
</tr>
</tbody>
</table>

#### 4.2. Most important symptoms and effects, both acute and delayed

Note: no information available

#### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physician: treat symptomatically - preserve blood and urine samples

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

<table>
<thead>
<tr>
<th>Media</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suitable extinguishing media</td>
<td>- water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions</td>
</tr>
<tr>
<td>Flash point (liquid)</td>
<td>not applicable</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>- full water jet</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific hazards</td>
<td>- formation of toxic and corrosive combustion gases (ammonia, hydrogen chloride, nitrogen oxides) possible</td>
</tr>
</tbody>
</table>

#### 5.3. Advice for firefighters

<table>
<thead>
<tr>
<th>Advice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection of fire-fighters</td>
<td>- precipitate gases/vapours/mists with water spray - chemical incident emergency response unit with full protective equipment</td>
</tr>
</tbody>
</table>
SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - prevent any exposure

6.2. Environmental precautions

Environmental protection - do not allow to enter drains or waterways

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect solids (avoid dust formation) and hand over to waste removal
- clean contaminated areas with little ethanol

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - aluminium, glass, stainless steel, enamel, polyethylene

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - below 30 °C
- in closed containers
- protected from light

Validity - see "best use before" date stated on the label
- 36 months, ≤30 °C, see "best use before" date stated on the label

Packaging materials - amber glass bottles with child resistant plastic closure
- polyethylene bag in metal drum

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.008 mg/m³

8.2. Exposure controls

General protective and hygiene measures - instruction of employees mandatory
- cleanse skin thoroughly after work, apply skin cream

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- in case of open handling or accidental release:
  particle mask or respirator with independent air supply
Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses

*1 referring to: Valganciclovir hydrochloride

**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>Color</td>
<td>white to slightly yellow</td>
</tr>
<tr>
<td>Form</td>
<td>granules</td>
</tr>
<tr>
<td>Solubility</td>
<td>10'370 mg/l, ethanol 95 %</td>
</tr>
<tr>
<td></td>
<td>~ 30 mg/l, acetone</td>
</tr>
<tr>
<td></td>
<td>~ 2'990 mg/l, hexane</td>
</tr>
<tr>
<td></td>
<td>~ 70'000 mg/l, water</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>log $P_{ow}$ 0.009 (n-octanol/buffer°C) pH 6.9</td>
</tr>
<tr>
<td>Melting temperature</td>
<td>175 °C (with decomposition)</td>
</tr>
</tbody>
</table>

9.2. Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissociation constant</td>
<td>$pK_1$ 7.6</td>
</tr>
</tbody>
</table>

**Solubility properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrolysis</td>
<td>hydrolytically unstable, in alkaline solution</td>
</tr>
</tbody>
</table>

*1 referring to: Valganciclovir hydrochloride

**SECTION 10: Stability and reactivity**

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available
10.4. Conditions to avoid

Conditions to avoid
- warming
- humidity

10.5. Incompatible materials

Materials to avoid
- strong oxidizing agents

10.6. Hazardous decomposition products

Note
- tends to racemise and hydrolyse quickly in neutral and basic aqueous solution

*1 referring to: Valganciclovir hydrochloride

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- LD$_{50}$ > 2'000 mg/kg (oral, mouse)

Local effects
- skin: non-irritant (rabbit)
- eye: irritant
- skin: slightly irritating (rabbit)

Sensitization
- non-sensitizing (guinea pig)

Chronic toxicity
- NOAEL 2 mg/kg/d (oral, rat; 90 days)

Mutagenicity
- mutagenic

Carcinogenicity
- carcinogenic

Reproductive toxicity
- teratogenic and embryotoxic
- may lower parental fertility

Note
- causes testicular atrophy, renal and hematologic changes

Potential Health Effects
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Valganciclovir hydrochloride
*2 referring to: Fumaric acid
*3 referring to: Ganciclovir
12.1. Toxicity

Ecotoxicity
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC\(_{50}\) (48 h) > 1010 mg/l (average measured concentration)
  NOEC (48 h) 1010 mg/l (average measured concentration) \(^*3\)
- barely toxic for fish (rainbow trout)
  LC\(_{50}\) (96 h) > 1020 mg/l (average measured concentration)
  NOEC (96 h) 1020 mg/l (average measured concentration) \(^*3\)
- barely toxic for fish (bluegill sunfish)
  LC\(_{50}\) (96 h) > 1020 mg/l (average measured concentration)
  NOEC (96 h) 1020 mg/l (average measured concentration) \(^*3\)
- barely toxic for bluegreen algae (nominal concentration > 100 mg/l) (Nostoc sp.)
  NOEC (12 d) 1000 mg/l
  (FDA Technical Assistance Document No. 4.02) \(^*3\)
- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture)
  NOEC 1000 mg/l \(^*3\)
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC\(_{50}\) (48 h) 212 mg/l \(^*2\)
- zebrafish
  LC\(_{50}\) (48 h) 245 mg/l \(^*2\)
- Desmodesmus (=Scenedesmus) subspicatus
  EC\(_{50}\) (72 h) 41 mg/l \(^*2\)

12.2. Persistence and degradability

Inherent biodegradability
- not inherently biodegradable
  2 %, 28 days \(^*3\)
- evidence for medium-term biodegradation in surface waters
  34 %, 28 d
  (analogous to OECD 308, Transformation in natural water/sediment systems) \(^*3\)

12.3. Bioaccumulative potential

Note
- no information available

12.4. Mobility in soil

Mobility
- barely volatile (water-air)
  \(K_{ow} = 0.00000026\) Pa\(\cdot\)m\(^3\)/mol (vapor pressure/water solubility) \(^*3\)

12.5. Results of PBT and vPvB assessment

Note
- no information available
12.6. Other adverse effects

Note - no information available

*2 referring to: Fumaric acid
*3 referring to: Ganciclovir

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal
- return to supplier or hand over to authorized disposal company
- medicines should not be disposed of via wastewater

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Safety-lab number - BS-6697

Note - Valganciclovir is a valyl ester prodrug of ganciclovir, which after oral administration is rapidly and extensively converted to ganciclovir during the absorption process

Edition documentation - changes from previous version in sections 1, 2, 3, 7, 9, 16

*1 referring to: Valganciclovir hydrochloride

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.