

Safety Data Sheet

# VALCYTE(R) Powder for Oral Solution (50 mg/ml)

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

### 1.1. Product identifier

Product name VALCYTE(R) Powder for Oral Solution (50 mg/ml)  
Product code SAP-10090308  
Synonyms - VALCYTE Powder for Oral Solution 50 mg/ml  
- VALCYTE Dry Syrup 250 mg/5 ml

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

Use - pharmaceutical active substance (virostatic) \*1

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

Company information Enquiries: Local representation:  
Genentech, Inc.  
1 DNA Way  
South San Francisco  
USA-CA 94080  
United States of America  
  
Phone 001-(650) 225-1000  
E-Mail info.sds@roche.com  
US Chemtrec phone:  
(800)-424-9300

### 1.4. Emergency telephone number

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

\*1 referring to: Valganciclovir hydrochloride

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## 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**

**Concentration**

**GHS-Classification  
(pure ingredient)**

Valganciclovir hydrochloride  
175865-59-5

~ 46 %

- Combustible dust (No category), USH003
- Germ cell mutagenicity (Category 1A), H340
- Carcinogenicity (Category 1A), H350
- Reproductive toxicity (Category 1A), H360FD
- Specific target organ toxicity - Repeated exposure (Category 1), H372

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Fumaric acid ~ 2 %  
110-17-8

*For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.*

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- |              |   |
|--------------|---|
| Eye contact  | - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly<br>- begin with medical treatment. |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents           |
| Inhalation   | - remove the casualty to fresh air and keep him/her calm<br>- get medical treatment                                   |
| Ingestion    | - summon a physician immediately  |

### 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<br>- preserve blood and urine samples |
|-------------------|---|

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- |                                |   |
|--------------------------------|---|
| Suitable extinguishing media   | - water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions |
| Flash point (liquid)           | not applicable  |
| Unsuitable extinguishing media | - full water jet  |

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

- |                  |  |
|------------------|--|
| Specific hazards | - formation of toxic and corrosive combustion gases (ammonia, hydrogen chloride, nitrogen oxides) possible |
|------------------|--|

### 5.3. Advice for firefighters

- |                             |  |
|-----------------------------|--|
| Protection of fire-fighters | - precipitate gases/vapours/mists with water spray<br>- chemical incident emergency response unit with full protective equipment |
|-----------------------------|--|

## 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/m<sup>3</sup> \*1

### 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

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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

Color	white to slightly yellow	
Form	granules	
Solubility	10'370 mg/l, ethanol 95 %	*1
	~ 30 mg/l, acetone	*1
	~ 2'990 mg/l, hexane	*1
	~ 70'000 mg/l, water	*1
Partition coefficient	log P <sub>ow</sub> 0.009 (n-octanol/buffer°C) pH 6.9	*1
Melting temperature	175 °C (with decomposition)	*1

### 9.2. Other information

Dissociation constant	pK <sub>1</sub> 7.6	*1
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#### Solubility properties

Hydrolysis	hydrolytically unstable, in alkaline solution	*1
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\*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

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### 10.4. Conditions to avoid

Conditions to avoid                    - warming  
   - humidity

### 10.5. Incompatible materials

Materials to avoid                    - strong oxidizing agents                    \*1

### 10.6. Hazardous decomposition products

Note                                        - tends to racemise and hydrolyse quickly in neutral and basic aqueous solution                    \*1

\*1 referring to:                        Valganciclovir hydrochloride

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity                         - LD<sub>50</sub>                    > 2'000    mg/kg    (oral, mouse)                    \*1

Chronic toxicity                       - NOAEL 2 mg/kg/d (oral, rat; 90 days)                    \*1

Local effects                           - skin: non-irritant (rabbit)                    \*1  
   - eye: irritant                                        \*2  
   - skin: slightly irritating (rabbit)                    \*2

Sensitization                         - non-sensitizing (guinea pig)                    \*1

Mutagenicity                           - mutagenic                                        \*1

Carcinogenicity                       - carcinogenic                                    \*3

Reproductive toxicity                - teratogenic and embryotoxic                    \*3  
   - may lower parental fertility                    \*3

STOT-single exposure                - no information available

STOT-repeated exposure            - no information available

Aspiration hazard                    - no information available

Note                                       - causes testicular atrophy, renal and hematologic changes                    \*1

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

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecotoxicity	<ul style="list-style-type: none"> <li>- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC<sub>50</sub> (48 h) &gt; 1010 mg/l (average measured concentration) NOEC (48 h) 1010 mg/l (average measured concentration) *3</li> <li>- barely toxic for fish (rainbow trout) LC<sub>50</sub> (96 h) &gt; 1020 mg/l (average measured concentration) NOEC (96 h) 1020 mg/l (average measured concentration) *3</li> <li>- barely toxic for fish (bluegill sunfish) LC<sub>50</sub> (96 h) &gt; 1020 mg/l (average measured concentration) NOEC (96 h) 1020 mg/l (average measured concentration) *3</li> <li>- barely toxic for bluegreen algae (nominal concentration &gt; 100 mg/l) (<i>Nostoc</i> sp.) NOEC (12 d) 1000 mg/l (FDA Technical Assistance Document No. 4.02) *3</li> <li>- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 1000 mg/l *3</li> <li>- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC<sub>50</sub> (48 h) 212 mg/l *2</li> <li>- zebrafish LC<sub>50</sub> (48 h) 245 mg/l *2</li> <li>- <i>Desmodesmus</i> (=Scenedesmus) subspicatus EC<sub>50</sub> (72 h) 41 mg/l *2</li> </ul>
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### 12.2. Persistence and degradability

Inherent biodegradability	<ul style="list-style-type: none"> <li>- not inherently biodegradable 2 %, 28 days *3</li> <li>- evidence for medium-term biodegradation in surface waters 34 %, 28 d (analogous to OECD 308, Transformation in natural water/sediment systems) *3</li> </ul>
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### 12.3. Bioaccumulative potential

Note - no information available

### 12.4. Mobility in soil

Mobility	<ul style="list-style-type: none"> <li>- barely volatile (water-air) K<sub>H</sub> = 0.00000026 Pa*m<sup>3</sup>/mol (vapor pressure/water solubility) *3</li> </ul>
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### 12.5. Results of PBT and vPvB assessment

Note - no information available

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## 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 as Dangerous Good according to the Dangerous Goods 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 and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

## SECTION 16: Other information

Safety-lab number - BS-6697

\*1

Full text of H-Statements referred to under section 3

H340 May cause genetic defects.

H350 May cause cancer.

H360FD May damage fertility. May damage the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

USH003 May form combustible dust concentrations in the air

## VALCYTE(R) Powder for Oral Solution (50 mg/ml)

- Note - Valganciclovir is a valyl ester prodrug of ganciclovir, which after oral administration is rapidly and extensively converted to ganciclovir during the absorption process \*1
- Edition documentation - changes from previous version in sections 2
- \*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.