

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: 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	Local representation:
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1.4. Emergency telephone number

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

*1 referring to: Valganciclovir hydrochloride

SECTION 2: Hazards identification

Emergency Overview

Form granules
 Color white to slightly yellow

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

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

Fumaric acid
110-17-8

~ 2 %

- Serious eye damage/eye irritation (Category 2A), H319

For the full text of the H-phrases mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	<ul style="list-style-type: none">- rinse immediately with tap water for 10 minutes - open eyelids forcibly- begin with medical treatment.
Skin contact	<ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	<ul style="list-style-type: none">- remove the casualty to fresh air and keep him/her calm- get medical treatment
Ingestion	<ul style="list-style-type: none">- summon a physician immediately

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

Note	<ul style="list-style-type: none">- no information available
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	<ul style="list-style-type: none">- treat symptomatically- preserve blood and urine samples
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	<ul style="list-style-type: none">- water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable
Unsuitable extinguishing media	<ul style="list-style-type: none">- full water jet

5.2. Special hazards arising from the substance or mixture

Specific hazards	<ul style="list-style-type: none">- formation of toxic and corrosive combustion gases (ammonia, hydrogen chloride, nitrogen oxides) possible
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5.3. Advice for firefighters

Protection of fire-fighters	<ul style="list-style-type: none">- precipitate gases/vapours/mists with water spray- chemical incident emergency response unit with full protective equipment
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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 *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 _{ow} 0.009 (n-octanol/buffer°C) pH 6.9	*1
Melting temperature	175 °C (with decomposition)	*1

9.2. Other information

Dissociation constant	pK ₁ 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 - LD₅₀ > 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"> - barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC₅₀ (48 h) > 1010 mg/l (average measured concentration) NOEC (48 h) 1010 mg/l (average measured concentration) *3 - barely toxic for fish (rainbow trout) LC₅₀ (96 h) > 1020 mg/l (average measured concentration) NOEC (96 h) 1020 mg/l (average measured concentration) *3 - barely toxic for fish (bluegill sunfish) LC₅₀ (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) (<i>Nostoc</i> 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 (<i>Daphnia magna</i>) EC₅₀ (48 h) 212 mg/l *2 - zebrafish LC₅₀ (48 h) 245 mg/l *2 - <i>Desmodemus</i> (= <i>Scenedesmus</i>) <i>subspicatus</i> EC₅₀ (72 h) 41 mg/l *2
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12.2. Persistence and degradability

Inherent biodegradability	<ul style="list-style-type: none"> - 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
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12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Mobility	<ul style="list-style-type: none"> - barely volatile (water-air) K_H = 0.00000026 Pa*m³/mol (vapor pressure/water solubility) *3
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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 (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

*1

Full text of H-Statements referred to under section 3

H319 Causes serious eye irritation.
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, 3, 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.