

Safety Data Sheet

VALCYTE(R) F.C. Tablets (450 mg)

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

1.1. Product identifier

Product name VALCYTE(R) F.C. Tablets (450 mg)

Product code SAP-10069575

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

VALCYTE(R) F.C. Tablets (450 mg)

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 81% Valganciclovir hydrochloride, with the remainder consisting of excipients that are not classified as hazardous

Ingredients

Concentration

Valganciclovir hydrochloride
CAS: 175865-59-5

81 %

Microcrystalline cellulose
CAS: 9004-34-6

7.8 %

VALCYTE(R) F.C. Tablets (450 mg)

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
------	--

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
-------------------	--

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
------------------	--

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
-----------------------------	---

VALCYTE(R) F.C. Tablets (450 mg)

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

Packaging materials - high density polyethylene (HDPE) bottles with a child-resistant polypropylene screw cap

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air - ACGIH-TLV: 10 mg/m³ *2
- OSHA-PEL: 5 mg/m³ (respirable dust fraction) *2
- OSHA-PEL: 15 mg/m³ (total dust) *2
- NIOSH-REL: 5 mg/m³ (respirable dust fraction) *2
- NIOSH-REL: 10 mg/m³ (total dust) *2

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

VALCYTE(R) F.C. Tablets (450 mg)

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
*2 referring to:	Microcrystalline cellulose

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	pink pale red	
Form	oval, biconvex tablet	
Solubility	10'370 mg/l, ethanol 95 % ~ 30 mg/l, acetone ~ 2'990 mg/l, hexane ~ 70'000 mg/l, water	*1 *1 *1 *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
-----------------------	---------------------	----

Solubility properties

Hydrolysis	hydrolytically unstable, in alkaline solution	*1
------------	---	----

*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
------	----------------------------

VALCYTE(R) F.C. Tablets (450 mg)

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 *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

Local effects - skin: non-irritant (rabbit) *1

Sensitization - non-sensitizing (guinea pig) *1

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

Mutagenicity - mutagenic *1

Carcinogenicity - carcinogenic *3

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

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

*3 referring to: Ganciclovir

VALCYTE(R) F.C. Tablets (450 mg)

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for planktonic crustaceans (<i>Daphnia magna</i>) 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) (<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

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 _H = 0.00000026 Pa*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

*3 referring to: Ganciclovir

VALCYTE(R) F.C. Tablets (450 mg)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste from residues
- return to supplier or hand over to authorized disposal company
 - observe local/national regulations regarding waste disposal
 - incinerate in qualified installation with flue gas scrubbing
 - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

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 *1
- 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
 - 496.3 mg Valganciclovir hydrochloride per tablet is equivalent to 450 mg free base
- 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.