

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

- Additional Health Information
- Carcinogenicity: May cause cancer based on information on related materials.
 - Reproductive Toxicity: May cause birth defects based on information on related materials.
 - Since this material may affect reproductive capabilities and the developing fetus, females and males planning to have a child and pregnant women should exercise caution regarding potential exposure.
 - It is also advisable for nursing mothers to exercise caution regarding exposure.

3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Valganciclovir hydrochloride (milled) CAS: 175865-59-5	~ 83 %
Microcrystalline cellulose CAS: 9004-34-6	~ 8 %

4. First-aid measures

- Eye contact
- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
- Skin contact
- remove immediately contaminated clothes, wash affected skin with plenty of water
- Inhalation
- in case of inhalation remove to fresh air and seek medical aid
- Ingestion
- consult physician

5. Fire-fighting measures

- Suitable extinguishing media
- water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid)
- not applicable
- Specific hazards
- Toxic emissions may be given off in a fire
- Protection of fire-fighters
- use self-contained breathing apparatus
- Special method of fire-fighting
- cool endangered containers with water spray

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6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Environmental protection	- avoid release to the environment
Methods for cleaning up	<ul style="list-style-type: none">- Scoop or shovel spilled material into a suitable labeled open head drum- Secure the drum cover and move the container to a safe holding area- Clean spill area thoroughly- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.- Check area for residual material and repeat clean up if detected

7. Handling and storage

Handling

Technical measures	<ul style="list-style-type: none">- local exhaust ventilation necessary- avoid dust formation; consider dust explosion hazard
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Storage

Storage conditions	<ul style="list-style-type: none">- keep containers tightly closed- room temperature- store in a dry place
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8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Threshold value (USA) air	<ul style="list-style-type: none">- ACGIH-TLV: 10 mg/m³- OSHA-PEL: 5 mg/m³ (respirable dust fraction)- OSHA-PEL: 15 mg/m³ (total dust)- NIOSH-REL: 5 mg/m³ (respirable dust fraction)- NIOSH-REL: 10 mg/m³ (total dust)	<ul style="list-style-type: none">*1*1*1*1*1
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 5 µg/m ³	*2

Personal protective equipment

Respiratory protection	<ul style="list-style-type: none">- 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 of larger quantities or accidental release: particle mask or respirator with independent air supply
Hand protection	- protective gloves
Eye protection	- safety glasses

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Body protection - protective clothing

*1 referring to: Microcrystalline cellulose

*2 referring to: Valganciclovir hydrochloride (milled)

9. Physical and chemical properties

Color pink

Form tablets

Solubility soluble, water

10. Stability and reactivity

Stability - stable under the conditions mentioned in chapter 7

Conditions to avoid - high temperatures

Materials to avoid - strong acids, oxidizing agents

Note - Hazardous polymerization: Will not occur

11. Toxicological information

Acute toxicity - LD₅₀ > 2'000 mg/kg (oral, mouse) *2
- LD₅₀ > 1'000 mg/kg (oral, dog) *2

Local effects - eye: non-irritant (rabbit) *2
- skin: non-irritant (rabbit) *2

Sensitization - non-sensitizing (guinea pig) *2

Chronic toxicity - NOEL 2 mg/kg/d (oral, rat; 90 days) *2
- NOAEL 1 mg/kg/d (oral, mouse; 180 days) *2
- NOEL < 0.2 mg/kg/d (oral, dog; 90 days) *2

Mutagenicity - mutagenic *2

Carcinogenicity - carcinogenic *3

Note - excretion is mainly renal *2
- elimination half-life: 5 h *2
- after oral administration ester hydrolysis to the active substance Ganciclovir *2
- occurs testicular atrophy, renal and hematologic changes *2

*2 referring to: Valganciclovir hydrochloride (milled)

*3 referring to: Ganciclovir

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12. Ecological information

Inherent biodegradability	<ul style="list-style-type: none"> - not inherently biodegradable 2 %, 28 days *3 - evidence for medium-term biodegradation in surface waters *3 - evidence for medium-term biodegradation in surface waters 34 %, 28 d (analogous to OECD 308, Transformation in natural water/sediment systems) *3 - inherently biodegradable *1
Ecotoxicity	<ul style="list-style-type: none"> - barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 1000 mg/l *3 - barely toxic for planktonic crustaceans (Daphnia magna) 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) (Nostoc sp.) NOEC (12 d) 1000 mg/l (FDA Technical Assistance Document No. 4.02) *3
Mobility	<ul style="list-style-type: none"> - barely volatile (water-air) K_H = 0.00000026 Pa*m³/mol (vapor pressure/water solubility) *3
*1 referring to:	Microcrystalline cellulose
*3 referring to:	Ganciclovir

13. Disposal considerations

Waste from residues	<ul style="list-style-type: none"> - incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - 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.
Contaminated packaging	<ul style="list-style-type: none"> - Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	<ul style="list-style-type: none"> - not regulated under RCRA

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14. Transport information

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

15. Regulatory information

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 enter a waterway or into soil, or 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.

16. Other information

Edition documentation - first edition

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.