

**Material Safety Data Sheet****VALCYTE(R) Powder for Constitution****1. Product and Company Identification**

Product name VALCYTE(R) Powder for Constitution

Product code 10061366

Use - Therapeutic Category: Antiviral

Company information Enquiries:
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2. Hazards identification**Emergency Overview**

Form powder

Color white to slightly yellow

Hazard Overview

- May cause blood system changes.
- May cause birth defects based on information on related materials
- May cause reproductive systems effects based on information on related materials
- Possible dust explosion hazard based on information on related materials

Potential Health Effects

- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: Hematopoietic/blood system
- Acute Effects: May cause eye irritation., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients.
- Chronic Effects: May cause blood system effects.
- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

Additional Health Information

- Reproduction Toxicity: May cause birth defects based on information on related materials.
- Since this material may affect reproductive capability and the developing fetus, females and males planning to have a child and pregnant women should exercise caution regarding exposure.

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- It is also advisable for nursing mothers to exercise caution regarding exposure.

3. Composition/Information on ingredients

Ingredients	Concentration
Valganciclovir hydrochloride CAS: 175865-59-5	~ 46 %
Fumaric acid CAS: 110-17-8	~ 2 %

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	- consider dust explosion hazard
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

6. Accidental release measures

Personal precautions	- ensure adequate ventilation
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7. Handling and storage

Handling

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|--------------------|---|
| Technical measures | <ul style="list-style-type: none">- Use with adequate ventilation- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)- avoid dust formation; consider dust explosion hazard- take precautionary measures against electrostatic charging |
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Storage

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| Storage conditions | <ul style="list-style-type: none">- 2 - 25 °C- dry and ventilated place |
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8. Exposure controls/Personal protection

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| Engineering Measures | <ul style="list-style-type: none">- see 7. |
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| Threshold value (Roche) air | <ul style="list-style-type: none">- IOEL (Internal Occupational Exposure Limit): 5 µg/m³ | *1 |
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Personal protective equipment

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|------------------------|--|
| 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.- Respiratory protection is recommended for dusty operations.- Use of a negative pressure air purifying, half face respirator with a toxic/dust/mist/fume high efficiency filter in the laboratory or a supplied-air full facepiece respirator or supplied-air hood for production operations is recommended. |
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| Hand protection | <ul style="list-style-type: none">- protective gloves |
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| Eye protection | <ul style="list-style-type: none">- tightly fitting safety glasses |
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- | | |
|-----------------|---|
| Body protection | <ul style="list-style-type: none">- protective clothing |
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| General protective and hygiene measures | <ul style="list-style-type: none">- instruction of employees mandatory- shower after work recommended |
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*1 referring to: Valganciclovir hydrochloride

9. Physical and chemical properties

Color	white to slightly yellow
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Form	powder
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10. Stability and reactivity

Stability	- stable under normal conditions
Materials to avoid	- strong oxidizing agents

11. Toxicological information

Acute toxicity	- LD ₅₀ > 2'000 mg/kg (oral, mouse)	*1
	- LD ₅₀ > 1'000 mg/kg (oral, dog)	*1
Local effects	- eye: non-irritant (rabbit)	*1
	- skin: non-irritant (rabbit)	*1
	- skin: slightly irritating (rabbit)	*2
	- eye: moderately irritating (rabbit)	*2
Sensitization	- non-sensitizing (guinea pig)	*1
Chronic toxicity	- NOEL 2 mg/kg/d (oral, rat; 90 days)	*1
	- NOAEL 1 mg/kg/d (oral, mouse; 180 days)	*1
	- NOEL < 0.2 mg/kg/d (oral, dog; 90 days)	*1
Mutagenicity	- mutagenic	*1
Note	- excretion is mainly renal	*1
	- elimination half-life: 5 h	*1
	- after oral administration ester hydrolysis to the active substance Ganciclovir	*1
	- occurs testicular atrophy, renal and hematologic changes	*1
*1 referring to:	Valganciclovir hydrochloride	
*2 referring to:	FUMARIC ACID	

12. Ecological information

Inherent biodegradability	- not inherently biodegradable 2 %, 28 days	*3
	- evidence for medium-term biodegradation in surface waters	*3
Ecotoxicity	- 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) > 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
	- Oncorhynchus kisutch LC ₅₀ (24 weeks) 10 mg/l	*2
	- Daphnia magna EC ₅₀ (48 hours) 212 mg/l	*2

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Mobility	- barely volatile (water-air) $K_H = 0.00000026 \text{ Pa} \cdot \text{m}^3/\text{mol}$ (vapor pressure/water solubility)	*3
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*2 referring to:	FUMARIC ACID
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*3 referring to:	Ganciclovir
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13. Disposal considerations

Waste from residues	- observe local/national regulations regarding waste disposal - incinerate in qualified installation with flue gas scrubbing
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RCRA waste	- not regulated under RCRA
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14. Transport information

Note	- not classified by transport regulations, proper shipping name non-regulated
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15. Regulatory information

TSCA Status	- FDA Exemption - not on inventory
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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.
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16. Other information

Edition documentation	- changes from previous version in sections 1
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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.