



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:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Phone 001-973/235 50 00
E-Mail info.sds@roche.com

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

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

- Technical measures
- 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

Storage

- Storage conditions
- 2 - 25 °C
 - dry and ventilated place

8. Exposure controls/Personal protection

- Engineering Measures
- see 7.

- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 5 µg/m³ *1

Personal protective equipment

- 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.
 - 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.

- Hand protection
- protective gloves

- Eye protection
- tightly fitting safety glasses

- Body protection
- protective clothing

- General protective and hygiene measures
- instruction of employees mandatory
 - shower after work recommended

*1 referring to: Valganciclovir hydrochloride

9. Physical and chemical properties

Color white to slightly yellow

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

*2 referring to: FUMARIC ACID

*3 referring to: Ganciclovir

13. Disposal considerations

Waste from residues - observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing

RCRA waste - not regulated under RCRA

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 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 - changes from previous version in sections 1

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.