

Safety Data Sheet

CYTOVENE(R) IV (500 mg/vial)

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

1.1. Product identifier

Product name CYTOVENE(R) IV (500 mg/vial)

Product code SAP-10051872

Synonyms - CYMEVENE lyophilized Vials
- CYTOVENE lyophilized Vials

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use - pharmaceutical active substance with antiviral effect *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: Ganciclovir

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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 further information available

SECTION 3: Composition/information on ingredients

Characterization synthetic guanine derivative ganciclovir sodium

Ingredients

Concentration

GHS-Classification (pure ingredient)

Ganciclovir Sodium
84245-13-6

100 %

- 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

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

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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- consult a physician |
| Skin contact | <ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents- consult physician |
| Inhalation | <ul style="list-style-type: none">- remove the casualty to fresh air and keep him/her calm- get medical treatment |

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 |
|-------------------|--|

SECTION 5: Firefighting measures

5.1. Extinguishing media

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|------------------------------|---|
| Suitable extinguishing media | <ul style="list-style-type: none">- water spray jet, dry powder, foam, carbon dioxide |
| Flash point (liquid) | not applicable |

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, 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- do not inhale explosion and/or combustion gases- avoid skin contact- use self-contained breathing apparatus |
|-----------------------------|--|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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|----------------------|---|
| Personal precautions | <ul style="list-style-type: none">- ensure adequate ventilation |
|----------------------|---|

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6.2. Environmental precautions

- Environmental protection
- do not allow to enter drains or waterways
 - if the substance reaches waters or the sewer system, inform the competent authority

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Technical measures
- 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

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions
- below 30 °C
 - protected from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 5 µg/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
- Hand protection
- protective gloves (neoprene, nitrile or butyl rubber)
- Eye protection
- safety glasses
- Analytcs
- sampling on glassfiber filter and chemical determination of the active compound (eg HPLC)

*1 referring to: Ganciclovir

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white to off-white	
Form	lyophilized powder	
Odor	odourless	
Solubility	2'670 mg/l, water (pH 7)	*1
Melting temperature	242 to 255 °C (with decomposition)	*1

9.2. Other information

Note - no information available

*1 referring to: Ganciclovir

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Materials to avoid - strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products - oxides of nitrogen

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀ > 2'000 mg/kg (oral, mouse)	*1
Local effects	- skin: non-irritant	*1
Carcinogenicity	- carcinogenic	*1
Reproductive toxicity	- teratogenic and embryotoxic - may lower parental fertility	*1 *1
Note	- dosage (oral): 1'000 mg (adults) - recommended daily dose: 3'000 mg/d - elimination half-life: 5 h - excretion is mainly renal - side effect(s) during therapy: changes in blood count	*1 *1 *1 *1 *1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Carcinogenicity: formulation not listed by NTP, IARC or OSHA	
*1 referring to:	Ganciclovir	

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- 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)	*1
	- 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)	*1
	- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 1000 mg/l	*1

12.2. Persistence and degradability

Inherent biodegradability	- not inherently biodegradable 2 %, 28 days	*1
	- evidence for medium-term biodegradation in surface waters	*1

12.3. Bioaccumulative potential

Note	- no information available	
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12.4. Mobility in soil

Note	- no information available	
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12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Ganciclovir

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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

Full text of H-Statements referred to under section 3

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

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Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 2, 3, 16

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.