

**1. Product and Company Identification**

Product name	CYTOVENE(R) Capsules (500 mg)
Product code	CSE-3021
Use	- CYTOVENE(R) is an antiviral agent indicated for the treatment of cytomegalovirus (CMV) infection in immunocompromised patients.
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America  Local representation:  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	capsules
Color	yellow-green
Hazard Overview	- May cause blood system changes. - May cause cancer based on animal data. - May cause birth defects based on animal data. - may cause reproductive system effects based on animal data
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Target Organs: gastrointestinal system, Hematopoietic/blood system, Male reproductive system, Female reproductive system  - Acute Effects: This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.  - Chronic Effects: May cause blood system changes., May affect bone marrow cell production.  - Carcinogenicity: May cause cancer based on animal studies., formulation not listed by NTP, IARC or OSHA - Carcinogenicity: IARC Gr3 not classifiable

\*1

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- Additional Health Information
- Reproductive Toxicity: May cause birth defects based on animal data. May cause reproductive system effects based on animal data.
  - 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 exposure.
  - It is also advisable for nursing mothers to exercise caution regarding exposure.

\*1 referring to: POVIDONE K 90

### 3. Composition/Information on ingredients

Characterization	final product
<b>Ingredients</b>	<b>Concentration</b>
Ganciclovir CAS: 82410-32-0	~ 92 %
Povidone K 90 CAS: 9003-39-8	~ 3 %

### 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

- |                          |                                                                                                                                                                                                                                                                                                                                                                                    |
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| Personal precautions     | - ensure adequate ventilation                                                                                                                                                                                                                                                                                                                                                      |
| Environmental protection | - avoid release to the environment                                                                                                                                                                                                                                                                                                                                                 |
| Methods for cleaning up  | - Scoop or shovel spilled material into a suitable labeled open head drum<br>- Secure the drum cover and move the container to a safe holding area<br>- Clean spill area thoroughly<br>- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.<br>- Check area for residual material and repeat clean up if detected |

### 7. Handling and storage

#### Handling

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| Technical measures | - local exhaust ventilation necessary |
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#### Storage

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| Storage conditions | - keep containers tightly closed<br>- room temperature<br>- store in a dry place<br>- protected from light |
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### 8. Exposure controls/Personal protection

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| Engineering Measures | - see 7. |
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| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 5 µg/m <sup>3</sup> | *2 |
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#### Personal protective equipment

- |                        |                                                                                                                                                                                                                                                                                                           |
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| 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.<br>- respiratory protection not necessary |
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| Hand protection | - protective gloves |
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| Eye protection | - safety glasses |
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| Body protection | - protective clothing |
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- |                  |             |
|------------------|-------------|
| *2 referring to: | Ganciclovir |
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## CYTOVENE(R) Capsules (500 mg)

### 9. Physical and chemical properties

Color	yellow-green
Form	capsules
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	- LD <sub>50</sub> > 2'000 mg/kg (oral, mouse)	*2
	- LD <sub>50</sub> > 1'000 mg/kg (oral, dog)	*2
	- LD <sub>50</sub> ~ 900 mg/kg (i.v., mouse)	*2
Local effects	- skin: non-irritant	*2
Carcinogenicity	- carcinogenic	*2
Reproduction toxicity	- teratogenic and embryotoxic	*2
	- may lower parental fertility	*2
Note	- dosage (oral): 1'000 mg (adults)	*2
	- recommended daily dose: 3'000 mg/d	*2
	- elimination half-life: 5 h	*2
	- excretion is mainly renal	*2
	- side effect(s) during therapy: changes in blood count	*2

\*2 referring to: Ganciclovir

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### 12. Ecological information

Inherent biodegradability	<ul style="list-style-type: none"> <li>- not inherently biodegradable 2 %, 28 days <span style="float: right;">*2</span></li> <li>- evidence for medium-term biodegradation in surface waters <span style="float: right;">*2</span></li> <li>- evidence for medium-term biodegradation in surface waters 34 %, 28 d (analogous to OECD 308, Transformation in natural water/sediment systems) <span style="float: right;">*2</span></li> </ul>
Ecotoxicity	<ul style="list-style-type: none"> <li>- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 1000 mg/l <span style="float: right;">*2</span></li> <li>- barely toxic for planktonic crustaceans (Daphnia magna) EC<sub>50</sub> (48 h) &gt; 1010 mg/l (average measured concentration) NOEC (48 h) 1010 mg/l (average measured concentration) <span style="float: right;">*2</span></li> <li>- barely toxic for fish (rainbow trout) LC<sub>50</sub> (96 h) &gt; 1020 mg/l (average measured concentration) NOEC (96 h) 1020 mg/l (average measured concentration) <span style="float: right;">*2</span></li> <li>- barely toxic for fish (bluegill sunfish) LC<sub>50</sub> (96 h) &gt; 1020 mg/l (average measured concentration) NOEC (96 h) 1020 mg/l (average measured concentration) <span style="float: right;">*2</span></li> <li>- barely toxic for bluegreen algae (nominal concentration &gt; 100 mg/l) (Nostoc sp.) NOEC (12 d) 1000 mg/l (FDA Technical Assistance Document No. 4.02) <span style="float: right;">*2</span></li> </ul>
Mobility	<ul style="list-style-type: none"> <li>- barely volatile (water-air) K<sub>H</sub> = 0.00000026 Pa*m<sup>3</sup>/mol (vapor pressure/water solubility) <span style="float: right;">*2</span></li> </ul>

\*2 referring to: Ganciclovir

### 13. Disposal considerations

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

### 14. Transport information

Note	<ul style="list-style-type: none"> <li>- not classified by transport regulations, proper shipping name non-regulated</li> </ul>
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### 15. Regulatory information

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| TSCA Status            | - FDA Exemption - not on inventory                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Reporting Requirements | <ul style="list-style-type: none"><li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li><li>- 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.</li><li>- State and local regulations vary and may impose additional reporting requirements.</li></ul> |

### 16. Other information

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| Edition documentation | - first edition |
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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.