Material Safety Data Sheet

CYTOVENE(R) Capsules (250 mg)

1. Product and Company Identification

Product name	CYTOVENE(R) Capsules (250 mg)
Product code	CSE-3020
Use	- CYTOVENE(R) is an antiviral agent indicated for the treatment of cytomegalovirus (CMV) infection in immunocompromised patients.
Company information	Enquiries: Local representation: 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	capsules
Color	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

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

Ingredients	**Concentration**
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

6. Accidental release measures

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 - 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	- local exhaust ventilation necessary

Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place - protected from light

8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 5 μg/m3	*2

Personal protective equipment

Respiratory protection	- Respiratory protection is recommended as a precaution to minimze 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 not necessary
Hand protection	- protective gloves
Eye protection	- safety glasses
Body protection	- protective clothing

*2 referring to: Ganciclovir

9. Physical and chemical properties

Color	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_{50}	> 2'000	mg/kg	(oral, mouse)	*2
	-	LD_{50}	> 1'000	mg/kg	(oral, dog)	*2
	-	LD_{50}	~ 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

12. Ecological information

Inherent biodegradability	- not inherently biodegradable 2 %, 28 days	*2
	- evidence for medium-term biodegradation in surface waters	*2
	- evidence for medium-term biodegradation in surface waters 34 %, 28 d (analogous to OECD 308, Transformation in natural water/sediment systems)	*2
Ecotoxicity	- barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 1000 mg/l	*2
	- 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)	*2
	- 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)	*2
	- 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)	*2
	- 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)	*2
Mobility	- barely volatile (water-air) K_H = 0.00000026 Pa*m3/mol (vapor pressure/water solubility)	*2

*2 referring to: Ganciclovir

13. Disposal considerations

Waste from residues	- 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	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
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	- 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.